UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	Chapter 11
PURDUE PHARMA L.P., *et al.*,	Case No. 19-23649 (RDD)
Debtors.[1]	Jointly Administered

DECLARATION OF LAWRENCE A. HAMERMESH

AUGUST 4, 2021

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

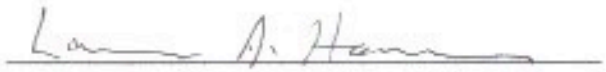
Under 28 U.S.C. § 1746, I, Lawrence A. Hamermesh, declare:

1. I submitted an expert report in this matter on June 15, 2021. Attached to this declaration is the corrected version of that report, which I submitted on July 12, 2021.

2. The corrected report constitutes my direct testimony in this matter. I declare under penalty of perjury that it is true and correct.

3. I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 4, 2021



Lawrence A. Hamermesh

In re Purdue Pharma, L.P. et al.
Case No. 19-23649 (RDD)

Expert Report of
Prof. Lawrence Hamermesh

Corrected as of
July 12, 2021

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	:	**Ch. 11**
PURDUE PHARMA, INC. et. al.,	:	**Case No. 19-23649 (RDD)**
Debtors.	:	**(Jointly Administered)**

EXPERT REPORT OF PROF. LAWRENCE A. HAMERMESH

Introduction

I am Professor Emeritus at Widener University Delaware Law School in Wilmington, Delaware, and Executive Director of the Institute for Law and Economics at the University of Pennsylvania Carey Law School. I have been retained by the law firms of Joseph Hage Aaronson LLC and Milbank LLP, as counsel for the Raymond Sackler family ("Counsel"),[1] to present expert testimony on matters of corporate governance practice involving the roles and activities of corporate directors and shareholders, and the policies underlying non-liability of directors and shareholders for corporate action or inaction.

Professional Background and Qualifications

1. Since 1994, I have been a professor at Delaware Law School, where I served as the Ruby R. Vale Professor of Corporate and Business Law. I have taught

[1] The Raymond Sackler family includes Richard Sackler, David Sackler, and the estates of the late Beverly Sackler and Jonathan Sackler, and certain persons and entities within the term "Covered Parties" as defined in the Amended and Restated Case Stipulation among the Debtors, the UCC, and Certain Related Parties in this matter, ¶5 (Sept. 15, 2019), ECF No. 518.

classes in business organizations, securities regulation, professional responsibility, corporate finance, mergers and acquisitions, and equity/equitable remedies. I have also been a visiting professor at the University of Pennsylvania Law School and the University of Michigan Law School, and I taught as an adjunct professor at New York University School of Law. I have served as Executive Director of the Institute for Law and Economics at the University of Pennsylvania Carey Law School since July 1, 2016. Through my career in academia, I have written and spoken extensively on business and corporate law, and have authored or co-authored numerous published articles or essays on those subjects. A true and correct copy of my resume is attached as Exhibit A. This includes a list of all publications that I have authored in the last ten years.

2. After graduating from Yale Law School in 1976, I practiced law at Morris, Nichols, Arsht & Tunnell in Wilmington, Delaware, where I was an associate from 1976 to 1984 and a partner from 1985 to 1994. At Morris Nichols, my practice focused on litigation involving the interpretation and application of duties (including fiduciary duties) of business entity managers, including corporate directors and officers as well as general partners of limited partnerships and members or managers of limited liability companies.

3. Since 1995, I have been a member of the Council of the Corporation Law Section of the Delaware State Bar Association, on which I served as Chair from 2002 until 2004. That Council has primary responsibility for reviewing, drafting, and proposing amendments to the Delaware General Corporation Law and for reviewing and approving proposed amendments to Delaware's other business entity laws.

4. From 2001 to 2007, I served as an appointed member of the American Bar Association ("ABA") Business Law Section's Corporate Laws Committee, which is responsible for drafting the Model Business Corporation Act and for preparing and publishing The Corporate Director's Guidebook, a compilation of commonly accepted propositions concerning the role and responsibilities of corporate directors. In 2011, I was appointed as Associate Reporter for that Committee, and I served as the Reporter from 2013 through 2020. I served as an elected member of the Council of the ABA Business Law Section from 2009-2012. From 2002-2003, I served as the Reporter for the ABA's Presidential Task Force on Corporate Responsibility, which published preliminary and final reports on corporate governance failures and reforms emerging from the Enron and WorldCom financial scandals.

5. I have also been appointed as an adviser to the American Law Institute's project to create a restatement of the law of corporate governance. From 2010 to 2011, I served as Special Counsel in the Office of Chief Counsel of the Division of Corporation Finance, of the U.S. Securities and Exchange Commission, in Washington, D.C. In that capacity, I advised that agency's staff on matters of state corporate law.

Nature of Engagement

6. In this report I address (a) the policies underlying liability or non-liability of directors for corporate action occurring while under the direction of the board of directors, (b) the customary and established norms of corporate governance for directors and whether the conduct of members of the Raymond Sackler family who served on the board of directors of Purdue Pharma Inc. ("PPI") (the "Former Directors") was consistent with those customary and established norms, and (c) the customary and established

norms of the control over a company exercised by direct or indirect beneficial owners of a company and whether the conduct of the Former Directors who were indirect beneficial owners of PPI and Purdue Pharma LP ("PPLP") (collectively, PPI and PPLP are "Purdue"), was consistent with the practice of beneficial shareholders applying customary and established norms of corporate governance.

7. In connection with this engagement, I have considered the materials listed in Exhibit B to this report, which I have reviewed in various levels of detail, and the Statement of Assumed Facts provided by Counsel that is set forth in Exhibit C. The recitation of facts set forth below is drawn from these sources. I respectfully reserve the right to supplement or modify this opinion if and as I am presented with additional factual information.

Compensation and Prior Expert Work

8. I am compensated for my work on this report at the rate of $750 per hour. No portion of my compensation is dependent on the nature of my opinions or the outcome of this proceeding.

9. A list of other proceedings in which I have testified as an expert at trial or by deposition within the last four years is attached as Exhibit D.

Summary of Opinions

10. Based on the information provided to me and the foundational assumption, explained below (in paragraph 12), that acts or omissions occurring before May 2007 (when certain of the Former Directors served in management capacities) are not pertinent to an assessment of liability of any of the Former Directors for the matters addressed in this report, it is my opinion that:

- A board of directors' oversight of a corporation's compliance mechanisms should comport with customary norms of corporate governance practice. Under those norms, directors can be expected to (i) take meaningful steps to confirm that effective systems exist for timely reporting to, and consideration by, the board of directors of systems of controls "designed to manage risk and and to provide reasonable assurance of compliance with law and corporate policies,"[2] and (ii) where those systems yield information indicating that the corporation "may be engaging in potentially unlawful or unethical conduct, promptly make further inquiry and follow up until they are reasonably satisfied that management is dealing with the situation appropriately."[3]
- The efforts made by the board of directors of PPI to establish and monitor the measures taken by PPLP and PPI from June 1, 2007 through December 2018 (the "Relevant Period")—during which members of the Raymond Sackler family served on PPI's board—to ensure compliance with applicable law and regulation, including to prevent deceptive marketing by PPLP and improper diversion of PPLP's opioids, are consistent with customary norms of corporate practice. Efforts made by the board of directors of PPI to establish and monitor PPLP's compliance program would not be regarded by persons familiar with corporate governance practices as a failure, much less as reflecting a sustained or systemic failure on the part of the directors of PPI, to implement effective controls and

[2] Corporate Laws Committee, ABA Business Law Section, *Corporate Director's Guidebook – 6th Edition*, 66 BUS. LAW. 975, 988 (2011) ("*Corporate Director's Guidebook*").

[3] *Id.* at 992.

information reporting regarding such matters.

- Customary norms of corporate governance practice also inform whether a board of directors' or individual director's activities are consistent with the roles and responsibilities of a corporate board or its members, or constitute personal participation in specific aspects of the corporation's work. Under those norms, a director can be expected to (i) devote substantial time to preparation for and participation in meetings of the board of directors and its committees, (ii) review materials supplied by management in connection with such meetings, (iii) request additional information reasonably necessary to making informed decisions, (iv) take steps to understand the corporation's business plan, the key drivers of its profitability, its regulatory, competitive, and financial risks, and its performance compared to its competitors, and (v) "participate on an informed basis, ask questions, challenge management as appropriate, apply considered business judgment to matters brought before the board, and when necessary, bring other matters to the full board's attention."[4]
- The activities of the members of the Former Directors during the Relevant Period did not constitute personal participation in the management of the business of PPI or PPLP, but rather would be regarded as consistent with customary norms of corporate practice by persons familiar with corporate governance practices.
- Customary norms of corporate governance practice also inform and guide the conduct of, and degree of control exercised by, the direct or indirect beneficial

[4] Corporate Director's Guidebook, 66 BUS. LAW. at 987-988.

owners of a corporation's stock. Consistent with those norms, the direct or indirect beneficial owners can be expected to seek representation on the corporation's board of directors, communicate with members of the board of directors (including members whom they nominated or designated to serve on the board) concerning the corporation's performance and business plans, and seek and obtain information from the corporation concerning such performance and business plans.[5]

- The members of the Raymond Sackler family, either individually or in combination, did not, directly or as indirect beneficial owners of PPI's stock and PPLP's limited partnership interests, act in a manner inconsistent with customary norms of corporate governance practices.

Sources of Factual Background

11. In addition to the customary norms and corporate governance practices with which I am familiar, the facts upon which I have based the opinions expressed herein are taken from the materials identified in Exhibit B and the Statement of Assumed Facts ("SAF") set forth in Exhibit C. Although I have had access to a database that I understand contains all documents produced by or to the Raymond Sackler family in these proceedings, I do not claim to be familiar with the entire universe of information disclosed, which I understand to be in excess of 100 million pages. I am not aware of

[5] *Compare* statutes, such as 6 Del. C. §17-303(b), which set forth a list of actions by limited partners that are deemed not to constitute participation in the control of the business and are therefore deemed not to be a basis for holding a limited partner liable for the obligations of the limited partnership.

facts that in my view would render the facts and assumptions on which this report is based materially inaccurate or incomplete.

12. As noted above, in this report I largely do not consider or address acts or omissions by any of the members of the Raymond Sackler family that occurred before May 2007. The reason for that chronological limit is my assumption that any claims potentially pertinent to this matter but based on acts or omissions occurring before May 2007 are precluded by consent judgments, settlements, and related releases entered into and approved by all states and the District of Columbia, primarily in 2007, or are otherwise untimely.[6] I do not express an opinion as to the validity or effect of those releases or the timeliness of such claims.

Summary of Claims and Pertinence of Assessment of Corporate Governance Practices

13. I address below three distinct types of claims asserted against members of the Raymond Sackler family:

- Claims that the Former Directors should be personally liable for harm allegedly caused by Purdue's allegedly improper marketing and failure to prevent the diversion of opioids because they failed to take adequate measures to detect and prevent such allegedly improper marketing and diversion.
- Claims that by direct participation in management of PPI (and, indirectly, PPLP), the Former Directors are personally liable for harm allegedly caused by Purdue's allegedly improper marketing of opioids or the diversion of Purdue's opioid products.

[6] West Virginia, the only state that did not enter into a 2007 consent judgment or settlement and related releases, had already entered into a similar settlement and release with PPLP, PPI and related Purdue entities in 2004. *See* SAF at ¶69.

- Claims that individual members of the Raymond Sackler family who served on PPI's board, insofar as they were acting as indirect beneficial owners of the shares of PPI and the limited partnership interests of PPLP, should be personally liable for harm allegedly caused by Purdue's allegedly improper marketing and failure to prevent the diversion of opioids because they exercised such control over PPI and PPLP that those entities should be regarded as agents for such family members.

14. The merits of these claims are of course controlled to a large extent by the applicable law (including especially New York corporate law, given that PPI is incorporated in New York). I do not consider it appropriate to present expert testimony about such matters of law to a tribunal capable of discerning and applying such law. To some extent, however, knowledge of normal, customary and accepted corporate governance practices may inform the application of governing legal principles. Thus:

- An understanding of normal, customary and accepted governance practices of corporate directors may inform whether the Former Directors did or did not systematically fail to take adequate measures to detect and prevent improper marketing or diversion of opioids.
- An understanding of normal, customary and accepted governance practices of corporate directors may inform whether the conduct of the Former Directors did or did not constitute direct participation in alleged corporate wrongdoing, or, alternatively, constituted ordinary and accepted action as directors (in which case, as noted below in paragraphs 17-22, liability would be inconsistent with the policies underlying culpability of directors for corporate action or inaction).

- Finally, an understanding of normal, customary and accepted governance practices in management of corporations and corporate subsidiaries may inform whether holding members of the Raymond Sackler family, individually or in combination, responsible for actions of PPI and PPLP on the theory that such entities should be viewed as having been the agents or alter ego of those family members as a matter of law would be inconsistent with the policies underlying liability or non-liability of directors and shareholders (direct and indirect) for corporate action or inaction.

Governance Setting

15. The operating business of Purdue was conducted, directly or through subsidiaries, by PPLP, a Delaware limited partnership. In that form of business organization, governance authority is exercised by one or more general partners, and economic interests are held by limited partners (which generally do not exercise managerial authority over the business of the partnership) and, typically to a much lesser extent, by general partners. In the case of PPLP, governance authority was exercised by PPI, a New York corporation, which at some times also held a very small limited partnership (economic) interest. The bulk of PPLP's limited partnership interests were held indirectly, through a series of Delaware limited partnerships, by trusts of which members of the Sackler families were beneficial owners.[7]

16. PPI's governance authority over PPLP was exercised through its board of directors, which included members of the Sackler families as well as non-family

[7] SAF ¶17.

members.[8] Ownership of PPI's stock has been held indirectly by, and split evenly between, the family of Mortimer Sackler (the "Side A") and the family of Raymond Sackler (the "Side B"). That split is addressed in PPI's articles of incorporation, which, during the Relevant Period, provided that (a) the board would be comprised of Class A directors, elected by the Side A, and Class B directors, elected by the Side B; and (b) no board action could be approved without the consent of a majority of each of the Side A directors and the Side B directors.[9] In other words, even if any one side's directors all acted together, neither the Side A directors nor the Side B directors could unilaterally take action at the board level.

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[8] The composition of the board of directors of PPI varied over time. In May 2007, for example, Mortimer D. Sackler, M.D., Theresa E. Sackler, Ilene Sackler Lefcourt, Raymond R. Sackler, M.D., Beverly Sackler, Richard S. Sackler, M.D., Kathe A. Sackler, M.D., Jonathan D. Sackler and Mortimer D.A. Sackler constituted the board of directors of PPI. *See* Exh. IS-1, PPLPUCC500140094-95. In August 2012, the members of the board of directors of PPI consisted of Theresa E. Sackler, Raymond R. Sackler, M.D., Beverly Sackler, Richard S. Sackler, M.D., Kathe A. Sackler, M.D., Jonathan D. Sackler, Mortimer D.A. Sackler, David Sackler, Ilene Sackler Lefcourt, Cecil B. Pickett, Peter Boer, Judith Lewent, Paulo Costa, and Ralph Snyderman. *See id*. In July 2018, the members of the board of directors of PPI consisted of Theresa E. Sackler, Mortimer D.A. Sackler, Ilene Sackler Lefcourt, Kathe A. Sackler, M.D., Cecil B. Pickett, Richard S. Sackler, M.D., Jonathan D. Sackler, David A. Sackler, Peter Boer and Steve Miller. *See id*.

[9] As amended in 2012, Article Third of PPI's articles of incorporation provided in relevant part:

> All actions by the Board of Directors of the Corporation shall be approved by the vote of each class of Directors voting separately, as follows:
>
> (i) A majority of the Class A Directors present at a meeting of the Board of Directors of the Corporation, and
>
> (ii) A majority of the Class B Directors present at a meeting of the Board of Directors of the Corporation.

Certificate of Amendment of Certificate of Incorporation of Purdue Pharma, Inc., at PPLP004415889. Before that amendment, PPI's articles contained substantively identical board voting approval requirements. Restated Certificate of Incorporation of Purdue Pharma, Inc., at PDD1506030031.

Overview of Corporate Law Policy

Director Non-Liability for Corporate Action

17. Corporate governance practices, including the scope of corporate directors' activities, exist within a framework established by state statute. For a New York corporation such as PPI, the key governing statute with regard to the conduct of directors is section 701 of the New York Business Corporation Law, which provides in pertinent part that "the business of a corporation shall be managed under the direction of its board of directors." The fact that the statute uses the term "under the direction of" rather than "by" reflects an important legal and practical reality: a board of directors does not conduct the business of the corporation itself; rather, corporate activities are conducted by the officers, employees, and agents of the corporation, through authority delegated to them, directly or indirectly, by the board of directors or the corporation's constitutent documents.[10]

[10] *Corporate Director's Guidebook*, 66 BUS. LAW. at 981 ("the board of directors oversees the business and affairs of the corporation and delegates to the officers the day-to-day operation of the enterprise."); *id.* at 986 ("typically, the board delegates management to officers and is then responsible for overseeing the corporation while management conducts the corporation's daily affairs."). *See also* David F. Larcker and Brian Tayan, Corporate Governance Research Initiative, Stanford Graduate School of Business, *Board of Directors Duties and Liabilities*, *available at* https://www.gsb.stanford.edu/sites/gsb/files/publication-pdf/cgri-quick-guide-03-board-directors-duties-liabilities.pdf ("The responsibilities of the board are separate and distinct from those of management. The board does not manage the company."); 1 WILLIAM E. KNEPPER & DAN A. BAILEY, LIABILITY OF CORPORATE OFFICERS AND DIRECTORS § 1.03 (8th ed. 2014) ("Although corporate statutes generally state that the business and affairs of a corporation are to be managed by or under the direction of directors, it is not practical or desirable for directors to actually manage the corporation."); AMERICAN LAW INSTITUTE, PRINCIPLES OF CORPORATE GOVERNANCE ("ALI PRINCIPLES") § 3.01 and Comment a (1994) ("The management of the business of a publicly held corporation … should be conducted by or under the supervision of such principal senior executives … as are designated by the board of directors," a principle that "reflects long-established corporate practice."). There are of course many corporations in which some or even all of

18. PPI's governance documents gave effect to this principle by stating that PPI's board of directors was not empowered to conduct the business of the corporation itself. The PPI By-Laws authorized the PPI board to control the "general management," *see* By-Laws (PUT000010519), and reserved to the PPI board "substantive matters **not** in the day-to-day ordinary course of business," such as budget approvals, new products, material acquisitions, and decisions about senior officers. *See* SAF ¶30 (emphasis added). The PPI By-Laws left the day-to-day business to the executives, who were charged with the obligation to "report to the President and CEO," who in turn were required to ensure that the PPI board received "all information necessary" about events that "would have a material effect on the business … ." SAF ¶32 .

19. Consistent with general principles regarding the allocation of managerial authority in a corporation, Section 717(a) of the New York Business Corporation Law recognizes the practical reality of customary board oversight—that directors necessarily rely on information and advice from corporate officers, employees and others engaged by and on behalf of the corporation. That statute provides in relevant part:

> … In performing his duties, a director shall be entitled to rely on information, opinions, reports or statements including financial statements and other financial data, in each case prepared or presented by:
>
> > (1) one or more officers or employees of the corporation or of any other corporation of which at least fifty percentum of the outstanding shares of stock entitling the holders thereof to vote for the election of directors is owned directly or indirectly by the corporation, whom the director believes to be reliable and competent in the matters presented,

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the directors also serve as officers or employees of the corporation, and conduct the corporation's business in those capacities. In the present matter, however, I am focusing on the Relevant Period, during which no member of the Raymond Sackler family occupied any management position with PPI or any of its subsidiaries other than as a director of PPI.

> (2) counsel, public accountants or other persons as to matters which the director believes to be within such person's professional or expert competence, or
>
> (3) a committee of the board upon which he does not serve, duly designated in accordance with a provision of the certificate of incorporation or the by-laws, as to matters within its designated authority, which committee the director believes to merit confidence, so long as in so relying he shall be acting in good faith and with such degree of care, but he shall not be considered to be acting in good faith if he has knowledge concerning the matter in question that would cause such reliance to be unwarranted. A person who so performs his duties shall have no liability by reason of being or having been a director of the corporation.

If reliance on information from those identified in this statute were not validated, it would be impossible for directors of a corporation with any significant business operations to oversee the management of the affairs of the corporation.

20. Another critical element of the customary, established and legal framework governing corporate practice and the role of corporate directors is that as an individual, an individual corporate director does not, and has no power or authority whatsoever to, make decisions for or take action on behalf of a corporation; a board of directors cannot act except as a collective body.[11] Thus, no individual director, as such, directly controls any aspect of corporate behavior.

21. Undoubtedly as a result of the practical realities of board service, the customary and established role of a director in corporate governance, and the related policies underlying this legal framework, there is no case of which I am aware in which a corporate director has been held legally responsible, due solely to service and action

[11] *Corporate Director's Guidebook*, 66 BUS. LAW at 981 ("directors exercise their decision-making powers only by acting collectively, either as a board or as a board committee.").

taken (or not taken) as a director, for harm caused by the corporation to any persons other than shareholders or the corporation itself.[12]

22. The absence of such legal responsibility serves important policies of corporate law and governance. A defining element of corporate governance is the placement of overall supervisory authority within a central institution, the board of directors. In a large scale business, that institution cannot effectively or meaningfully conduct all aspects of the corporation's business directly, and necessarily must delegate responsibility for those aspects to officers and agents, subject to a continuing obligation to exercise oversight. If directors were held responsible for aspects of the corporation's business that were subject to that oversight, they would effectively be constrained to become personally and directly familiar with all such aspects of the business. That outcome would have two consequences that would defeat the purpose of the corporate form and the centralization of authority in the board of directors: it would frustrate the ability of a corporation and its investors and other constituencies to reap the benefits of large scale activity; and it would impose potential liability upon directors that would

[12] Indeed, even senior corporate officers are generally not held personally liable to persons other than the corporation or its shareholders for wrongs done by the corporation, in the absence of personal participation on their part in such wrongs. *See, e.g., T.V. Spano Bldg. Corp. v. Dep't of Nat. Res. & Env't Control*, 628 A.2d 53, 61 (Del. 1993) (knowledge of wrongful corporate activity is insufficient as a basis for officer liability; the officer must have "directed, ordered, ratified, approved, or consented to" the wrongful conduct). Senior corporate officers may be held personally liable for wrongs done by the corporation in an area for which they are personally in a position of authority, under what is described as the "responsible corporate officer doctrine." *E.g., City of Newburgh v. Sarna*, 690 F. Supp. 2d 136, 160 (S.D.N.Y. 2010), *aff'd in relevant part*, 406 F. App'x 557 (2d Cir. 2011). That doctrine could apply to senior corporate officers who also serve as directors. I have found no case, however, in which that doctrine has been applied to impose liability on a director who did not also participate as an officer in the wrongdoing as to which liability was asserted.

dwarf any compensation they might receive as directors, thereby effectively discouraging anyone from serving as a director.

Policies Underlying Shareholder Liability or Non-Liability for Corporate Action

23. Corporate governance practices that inform the scope of shareholder activities are likewise informed by the framework established by state statute. The law governing the liability of shareholders for harm caused by corporate acts or omissions likewise stems from compelling policies that result in extreme reluctance to attribute corporate conduct to controlling shareholders (in other words, to "pierce the corporate veil").[13] Limited liability is a critical policy element of corporate law that serves to encourage investment in business enterprises. Corporations and corporate groups, and their creditors, rely on limited liability to assure a predictable status of claims against the corporation: the ability to rely on limited liability encourages extension of credit and reduces the cost of capital. By contrast, veil-piercing—that is, treating the corporation as the agent or alter ego of a controlling shareholder—threatens legitimate commercial expectations and makes the costs of investing and lending difficult to predict and, therefore, more expensive for all corporate stakeholders. As explained in a leading exposition of the policies underlying corporate law, the authors note that even in the case of a corporation that is the sole stockholder of a subsidiary:

> It does not follow that parent and affiliate corporations routinely should be liable for the debts of those in which they hold stock. Far from it. Such general liability

[13] Under New York law governing the liability of shareholders of a New York corporation like PPI, "courts disregard corporate form reluctantly, [and] … only when the form has been used to achieve fraud, or when the corporation has been so dominated by an individual or another corporation (usually a parent corporation), and its separate identity so disregarded, that it primarily transacted the dominator's business rather than its own and can be called the other's alter ego." *Gartner v. Snyder*, 607 F.2d 582, 586 (2d Cir. 1979). *See* discussion at paragraphs 53-58 below.

> would give small or unaffiliated firms a competitive advantage. Think of the taxicab business. Taxi firms may incorporate each cab or put just a few cabs in a firm. If courts routinely disregarded this arrangement and put the assets of the full venture at risk for the accidents of each cab, then "true" single-cab firms would have lower costs of operation because they alone could cut off liability. That would create a perverse incentive because … larger firms are apt to carry more insurance. Potential victims of torts would not gain from a legal rule that promoted corporate disintegration. Moreover, requiring a corporation to satisfy claims against its affiliate would induce creditors of each firm to monitor the others, squandering the benefits of creditors as specialized monitors of assets or projects. … As a result, courts properly disregard the corporate form rarely: only when the corporate arrangement has increased risks over what they would be if firms generally were organized as separate ventures.[14]

24. In light of these policy considerations, the applicable case law recognizes that many standard aspects of corporate groups (parent corporations and their direct and indirect subsidiaries) do not warrant piercing the corporate veil. Thus, large enterprises routinely derive the bulk of their value from business conducted through direct or indirect wholly-owned subsidiaries. Indeed, it is an accepted matter of law and corporate governance that a wholly-owned subsidiary is generally to be operated so as to serve the interests of the parent company and its stockholders, and not any putative independent interest of the subsidiary.[15] And yet despite that prevailing view, imposing liability on corporate parent entities or their direct or indirect majority shareholders or owners for corporate conduct in which they were not directly and personally involved remains reserved for extreme situations involving fraudulent conduct or similar abuse of the corporate form. [16]

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[14] Frank H. Easterbrook & Daniel R. Fischel, The Economic Structure of Corporate Law, at 57 (1991).

[15] *E.g., Anadarko Petroleum Co. v. Panhandle Eastern Corp.*, 545 A.2d 1171, 1174 (Del. 1988) ("in a parent and wholly-owned subsidiary context, the directors of the subsidiary are obligated only to manage the affairs of the subsidiary in the best interests of the parent and its shareholders.").

[16] Liability of a limited partner for the obligations of a limited partnership is likely even

Evaluation of Claims that the Former Directors of PPI Should Be Personally Liable for Failure to Detect and Prevent Improper Marketing or Diversion of Opioids

25. I have reviewed thousands of documents reflecting communications by or to the Former Directors from 2007 through 2018, but have not encountered any such communication in which a Former Director directed that (i) marketing of opioids be done in a fraudulent or deceptive manner, or (ii) PPLP not vigorously implement its anti-diversion efforts. Similarly, I have not encountered any such communication indicating either that improper marketing or diversion had occurred and was not being promptly and appropriately addressed by Purdue's compliance staff, or that any significant ongoing improper marketing or diversion had gone undetected by Purdue's system of internal controls. To the contrary, the records I have reviewed show that the board of directors actively monitored direct and regular reporting about PPLP's compliance and anti-diversion efforts and how those efforts satisfied its legal and regulatory obligations.

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less common, for several reasons. First, and unlike the situation with a corporation, a limited partnership always includes at least one person—a general partner who exercises control and is generally liable for all obligations of the limited partnership. *See, e.g.*, 6 Del. C. § 17-403(b) (a general partner "has the liabilities of a partner in a partnership that is governed by the Delaware Uniform Partnership Law," which in turn provides (in § 15-306(a)) in relevant part that "all partners are liable jointly and severally for all obligations of the partnership unless otherwise agreed by the claimant or provided by law."). Second, the limited partnership law of Delaware, which governs PPLP, specifies that (i) a limited partner who is not a general partner "is not liable for the obligations of a limited partnership" unless the limited partner "participates in the control of the business;" (ii) participation in control of the business expressly *excludes* an extensive list of activities (including consulting or advising the limited partnership or a general partner, "proposing, approving, consenting or disapproving, by voting or otherwise," on a wide range of matters including taking on debt, selling assets, and admission or removal of a general or limited partner, and providing management, consulting or advisory services to the limited partnership); (iii) even if a "limited partner does participate in the control of the business, he or she is liable only to persons who transact business with the limited partnership reasonably believing, based upon the limited partner's conduct, that the limited partner is a general partner." 6 Del. C. § 17-303.

26. Of course, many large businesses will from time to time have employees or agents who engage in improper conduct. Last year Purdue entered a guilty plea with respect to three aspects of its opioid marketing and anti-diversion programs.[17] Corporate directors could not rationally be expected to serve as directors and implement and supervise efforts to minimize such misconduct, however, if they were personally liable for harm arising from any such misconduct. The law recognizes the reality of this governance situation by implementing policies sharply limiting the liability of corporate directors for misconduct by corporate employees or agents: directors are liable for misconduct by others in the corporation only if they "(a) … utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, consciously failed to monitor or oversee its operations thus disabling

[17] None of the three counts in the 2020 plea agreement recites that any of the Former Directors were involved in or aware of the specified misconduct. *United States of America v. Purdue Pharma L.P.*, No. 2:20-cr-01028 (D.N.J. Nov. 24, 2020) ECF No. 6, Schedule A. *See generally* SAF ¶¶326-39. Count One involved the administration of Purdue's anti-diversion program, a program administered by Purdue management, as to which the board of directors of PPI received repeated assurances from management of legal compliance (*see* paragraphs 40-41 below); Count Two involved payments of speaker fees to two health care providers, but again, the PPI board received regular reports from management assuring that such payments were monitored and audited and no significant compliance issues were identified (*e.g.*, Report to Board of Directors – Post-CIA Compliance Program, July 19, 2012, PPLP004408046, at -069 (reporting commercial monitoring of "Speaker Programs" "to be continued/strengthened"); Corporate Compliance Quarterly Report to Board of Directors, PPLP004406032, at -035 ("a compliance monitoring program for speaker dinners is now in place. No compliance issues have presented to date."); Quarterly Compliance Report to the Board of Directors for 4Q 2013, PPLP004410797, at -808 (2013 audit to assess "whether there is a relationship between HCP prescribing of Purdue product, and any financial compensation received from Purdue" found "no correlation."); Quarterly Compliance Report to the Board of Directors for 2Q 2015, PPLP004412152, at -155 (italics in original) (audit found "*no correlation [ ] between Purdue's financial relationships with HCPs and their prescribing of Purdue products*."); and Count Three involved use of a marketing firm named Practice Fusion to promote sales of extended release opioids, but there is no indication that the PPI board was involved with or even aware of this initiative.

themselves from being informed of risks or problems requiring their attention."[18] The *Caremark* opinion that first articulated this formulation acknowledged that establishing director liability for acts or omissions of others in the corporation is "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment."[19]

Customary Norms of Director Oversight

27. At the same time, boards of directors are expected as a matter of custom and practice to do more to promote compliance with applicable law and effective risk management than the minimum level of effort to avoid legal liability. Accordingly, directors who engage in that more robust but customary level of effort should not be held personally liable for harm arising from corporate conduct within their sphere of oversight but in which they are not personally involved.

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[18] *Hughes v. Hu*, 2020 WL 1987029, at *14 (Del. Ch. Apr. 27, 2020) (quoting *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 370 (Del. 2006)); *L.A. Grika on behalf of McGraw Hill Fin., Inc. v. McGraw*, 57 N.Y.S.3d 675, 2016 WL 8716417, at *16 (N.Y. Sup. Ct. 2016), *aff'd*, 161 A.D.3d 450 (1st Dep't 2018) (applying New York law and looking to the *Caremark* standard).

[19] *In re Caremark Int'l., Inc. Deriv. Litig.*, 698 A.2d 959, 967 (Del. Ch. 1996); *accord Fisher ex rel. LendingClub Corp. v. Sanborn*, 2021 WL 1197577, at *9 (Del. Ch. Mar. 30, 2021) (quoting *Caremark*). The responsible corporate officer doctrine, as articulated, for example, in *U.S. v. Park*, 421 U.S. 658 (1975), may permit the imposition of liability upon corporate officers without proof of criminal intent or possibly even knowledge of corporate wrongdoing. As in *Park*, however, that doctrine has been applied only to corporate officers and "agents" (421 U.S. at 670-674, referring repeatedly to "corporate agents"). Directors as such, however, are neither corporate officers nor agents, and as noted in footnote 13 above, directors (like the Former Directors) who are not officers or agents have not to my knowledge been found liable under the responsible corporate officer doctrine. RESTATEMENT (THIRD) OF THE LAW OF AGENCY § 1.01 cmt. f(2) (2006) ("the directors are neither the shareholders' nor the corporation's agents as defined in this section, given the treatment of directors within contemporary corporation law in the United States.").

28. As noted in paragraph 10 above, directors are expected to take steps to confirm that effective systems exist for timely reporting to, and consideration by, the board of systems of controls "designed to manage risk and and to provide reasonable assurance of compliance with law and corporate policies,"[20] and where those systems yield information indicating that the corporation "may be engaging in potentially unlawful or unethical conduct, they can be expected to promptly make further inquiry and follow up until they are reasonably satisfied that management is dealing with the situation appropriately."[21]

29. During the Relevant Period, there were various sources of guidance elaborating on how a large corporation could establish and maintain a system that comported with the norms outlined above. One such source, perhaps most pertinent to Purdue, which was originally issued in 2003 by by the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS") for pharmaceutical businesses, described the following "seven elements that have been widely recognized as fundamental to an effective compliance program:

• Implementing written policies and procedures;
• Designating a compliance officer and compliance committee;
• Conducting effective training and education;
• Developing effective lines of communication;
• Conducting internal monitoring and auditing;
• Enforcing standards through well-publicized disciplinary guidelines; and
• Responding promptly to detected problems and undertaking corrective action."[22]

[20] Corporate Director's Guidebook, 66 BUS. LAW. at 988.

[21] *Id*. at 992.

[22] HHS-OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23732-33 (May 5, 2003), *available at*

30. For the reasons outlined above (paragraphs 17-22), it was not the responsibility of the Former Directors to create and operate these seven fundamental compliance program elements; rather, under customary norms of director conduct, it was the responsibility of the Former Directors to take reasonable measures to assure themselves that Purdue management created and operated those elements. Accordingly, I examine below whether the actions of the Former Directors in regard to implementation and monitoring of a reporting system and controls over marketing and distribution of opioids satisfied or exceeded the norms of customary corporate governance practice reflected in the guidance described above. The facts summarized[23] below are the basis for my opinion that they did.

Marketing

31. I first review the Former Directors' awareness of and conduct in connection with Purdue's reporting and controls system applicable to marketing of opioids during the Relevant Period. Preliminarily, I note that well-before 2007, the board of directors of PPI was aware that compliance problems in regard to marketing of opioids posed a significant risk to Purdue. Thus, by 2007, the Former Directors had already taken reasonable measures to satisfy themselves that the seven essential compliance program elements were in place: in 2005, while the federal investigation that resulted in Purdue's 2007 criminal guilty plea for conduct ending in 2001 was pending,[24] the PPI board

https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf. *See also* United States Sentencing Commission Guidelines Manual, § 8B2.1.

[23] The word "summarized" is critical: the factual recitation below on the subject of internal reporting and controls is not at all exhaustive, and omits many details that compellingly support the conclusions set forth in this report.

[24] Agreed Statement of Facts in U.S. v. The Purdue Frederick Company, Inc. *et al.*

adopted a compliance charter that required the company to implement a compliance program that satisfied the OIG guidance;[25] and on April 5, 2006, in a long series of management reports on corporate compliance efforts, the PPI board was advised that "[r]equirements [] of OIG Guidance [had been] established," and that the law firm of King & Spalding had successfully completed an audit to assess conformity with that guidance.[26] The Former Directors were assured in particular that "Sales and Marketing activities continue to be a primary focus of Corporate Compliance," with "OxyContin Promotion in new environment" identified as a "priority risk" for the Sales and Marketing Compliance Committee.[27]

32. Soon thereafter, Purdue became subject to more specific supplemental and binding compliance directives from the HHS OIG: from 2007 to 2012, a 38-page single spaced Corporate Integrity Agreement ("CIA") with the OIG:

- Noted that Purdue had already "established a voluntary compliance program (Corporate Compliance Program), which include[d] a corporate Compliance Officer and Corporate Compliance Council, a Code of Business Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and

(W.D.Va.), ¶¶ 6, 18, 20, 27, 37-38, 43-44 (May 9, 2007).

[25] *See* 2005 Corporate Compliance Charter (PKY183307471).

[26] 2005 Update / 2006 Budget dated Nov. 1, 2005 (PPLPC018000070210) at slide 39 ("Highly favorable King & Spalding audit"); April 5, 2006 Corporate Compliance Report to the Board of Directors (PPLPC031000329746) at slide 11 ("Successful King & Spaulding [*sic*] OIG Guidance audit 6/05"). The board was assured at the same that "[a]ll seven elements of the 2004 Sentencing Guidelines [had been] established." *Id.*

[27] *Id*. at slides 13-14.

interna1 review procedures designed, as represented by Purdue, to promote compliance with applicable laws and the promotion of high ethical standards."[28]

- Required the Compliance Officer to "make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Purdue."[29]
- Required Purdue's written policies and procedures to address the "selling, marketing, promoting, advertising, and disseminating Materials or information about Purdue's products in compliance with all applicable FDA requirements, including requirements relating to the dissemination of information that is fair and accurate."[30]
- Required those policies to address compensation of employees "engaged in promoting and selling Purdue products that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion or sales of Purdue's products."[31]
- Required those policies to address "(i) the form and content of Materials disseminated by sales representatives; and (ii) the internal review process for the Materials and information disseminated by sales representatives" relating to "withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products."[32]

[28] CIA at 1.

[29] CIA at 4.

[30] CIA at 7.

[31] CIA at 7.

[32] CIA at 7-9.

- Required that all employees engaged in sales and marketing receive training on "all applicable FDA requirements relevant to promotion, marketing, research, and dissemination of medical or scientific information about Purdue's products."[33]
- Required Purdue to retain an Independent Review Organization ("IRO") to conduct a review of systems and transactions involving marketing of Purdue's products, including development of marketing materials, responses of sales representatives to inquiries about off-label uses of Purdue products, and provision of information related to "withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products."[34]
- Required Purdue to promptly report "anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or any FDA requirements relating to the labeling or promotion of products for which penalties or exclusion may be authorized."[35]
- Required Purdue's Compliance Officer twice a year to "review a random selection of 75 Focus Inquiries listed on the Focus Inquiry Report to identify situations in which the Compliance Officer believes a sales representative may have made improper statements about any Purdue product(s), including those

[33] CIA at 12.

[34] CIA Appendix B, part II.A.

[35] CIA at 19-20.

improper statements related to withdrawal, drug tolerance, drug addiction, drug abuse, or off-label uses of the product(s)."[36]

- Required Purdue to continue its "formalized process through which Purdue's District Managers evaluate and monitor sales representative interactions with" health care providers ("HCPs"), including "ride-alongs at least five full days of the interactions between each sales representative and HCPs during each Reporting Period."[37]
- Required Purdue to submit annual reports to the OIG certifying and setting forth detailed information about Purdue's compliance with the foregoing requirements.[38]

33. On May 11, 2007, the day after Purdue entered into the CIA, the PPI board amended Purdue's corporate compliance charter to incorporate the requirements of the CIA.[39]

34. During each of the five years in which the CIA was in force, the board of directors of PPI received regular quarterly reports from the Compliance Officer documenting Purdue's compliance with the letter and spirit of the CIA's requirements. The quarterly reports included detailed observations about the operation of Purdue's compliance mechanisms—including observations about the number of investigations that had been conducted and about minor problems that had been identified and remediated—thereby assuring the board that the compliance program was in effect. The quarterly

[36] CIA at 22.

[37] CIA at 23-24.

[38] CIA at 27-30.

[39] PPLP004416560 at -592.

reports also assured the board that the program was effective, by regularly indicating to the board that no significant compliance problems had been encountered and that any problems identified were minor and remediated.[40] And following its annual inspections (including site visits to Purdue facilities), the OIG never invoked the provisions of the CIA authorizing the imposition of penalties on Purdue or excluding it from participation in federal health care programs due to breach of the CIA.[41] To the contrary, the board of PPI was advised each year that the OIG had confirmed that "Purdue was in compliance with the terms of its Corporate Integrity Agreement during the [] reporting period."[42]

35. The Quarterly Compliance Report to the board dated November 3, 2010 specifically analyzed each of the seven elements of an effective compliance program, as determined by the OIG of HHS, and the manner in which Purdue had implemented each one, explaining how "Purdue's compliance program has also been implemented pursuant to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, and is continually reviewed and updated in light of current standards and emerging

[40] For example, the report to the board for the second quarter of 2008 recited that the Compliance Officer and his staff "investigated a total of 93 Hotline and other matters during the second quarter of 2008. None of these matters were of significant concern or indicative of compliance failures sufficient to warrant reporting to the Board or to applicable regulatory or other authorities." July 15, 2008 Purdue Quarterly Report to the Board (PPLP004367297) at -324. Similarly, the report for the second quarter of 2011 recited that "[a]ll requirements under the CIA have been met in Reporting Period 4, including all critical field-based CIA requirements," and with regard to "Marketing & Sales, there were "[n]o compliance shortcomings to report." August 3, 2011 Purdue Quarterly Report to the Board (PPLP004366913), at -915, -920, -940.

[41] The CIA sets forth those provisions at pp. 32-36.

[42] *E.g.*, April 21, 2010 Purdue Quarterly Report to the Board (PPLP004317547) at -559.

developments.[43] The report reviewed the "Seven Elements of an 'effective compliance program'" and enumerated how Purdue satisfied each.[44]

36. Accordingly, for the five year period in which the CIA was in force, no one familiar with corporate governance practices could in my opinion reasonably conclude that the Former Directors "(a) … utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, consciously failed to monitor or oversee [Purdue's] operations thus disabling themselves from being informed of risks or problems requiring their attention,"[45] at least as far as Purdue's opioid marketing practices were concerned. To the contrary, based on the information supplied by management with the respect to the five-year period from 2007 to 2012, and in light of the compliance system guidance from the HHS OIG, the U.S. Sentencing Guidelines, and the specific obligations imposed under the CIA, the Former Directors had ample bases to conclude, consistent with customary norms regarding the oversight responsibilities of corporate directors, that Purdue's program for assuring that OxyContin was being marketed in a manner consistent with applicable law and regulations was meaningfully effective.

37. For the period after the expiration of the CIA in 2012, there is a similar record of advice to the board of PPI concerning operation of the previously established system of controls and internal reporting regarding Purdue's marketing of its products.

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[43] *See* November 3, 2010 Quarterly Compliance Report (PPLP004405460) at -5465, -5467-493.

[44] *Id*. at PPLP004405467-93.

[45] *Hughes*, 2020 WL 1987029, at *14; *Grika*, 2016 WL 8716417, at *16.

- As the CIA approached expiration, management of Purdue made it clear to the board of directors of PPI that the regime of controls and monitoring that prevailed under the CIA would essentially continue (although without the direct involvement of the OIG and without the IRO requirement).[46]
- From 2013 to 2018, Purdue management regularly and repeatedly presented detailed reports to PPI's directors about Purdue's compliance activities, concluding with advice that there were "no significant compliance issues" to report, with regard to marketing of OxyContin or otherwise.[47]
- Purdue engaged outside independent counsel (Skadden Arps) to conduct continuing review of the operation of Purdue's compliance systems.[48] The board

[46] *E.g,* July 19, 2012 Corporate Compliance Department Report to Board of Directors – Post-CIA Compliance Program (PPLP004408046) at -048-55 ("Post-CIA there will be little change in Purdue's compliance program").

[47] *E.g.*, Purdue Quarterly Report to the Board, 1st Quarter, 2013 (May 13, 2013) (PPLP004367540) at -591 ("Throughout the First Quarter, the Company continues to maintain a state of effective compliance.... [T]here have been no significant compliance matters to report"); Quarterly Compliance Report to the Board, 3Q2012 (Oct. 28, 2013) (PPLP004410504) at -507, -512 ("There are no significant violations or gaps to report for the 3rd quarter of 2013;" and "Field Contact Reports (FCR)… are the best means for DMs [division managers] to monitor and correct sales representative performance in the field, including compliance," and "for full year 2013 … Compliance issues reported by DMs in FCRs are overwhelmingly administrative in nature (late-entered call notes, late expense reporting), and not of a substantive nature"); Quarterly Compliance Report to the Board, 4Q2014 (Jan. 16, 2015) (PPLP004411807) at -812 ("There have been no significant compliance issues in the 4th quarter, or in Full Year 2014"); Quarterly Ethics and Compliance Report to Board of Directors for 4Q2015 (March 09-10, 2016) (PPLP004412818) at -819 ("Purdue continues to have strong systems and processes in place to prevent and detect violations of law, regulations, and Company policies, and to remediate issues before they become significant problems. There have been no significant compliance issues in the 4th quarter, 2015."); Ethics and Compliance Update Pre-Read (March 2018) (PPLP004414931) at -932 ("No significant compliance issues to report.").

[48] 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 7 ("Have retained expert healthcare counsel, John Bentivoglio of Skadden Arps, to … [p]rovide ongoing reviews of Compliance Program effectiveness and improvements").

was informed that Mr. Bentivoglio and Skadden would "[p]rovide ongoing reviews of Compliance Program effectiveness and improvements," "[m]eet with Corporate Compliance Council and other select Committees as an outside resource," and "[c]onsult with [the] Compliance Department."[49]

- In 2015, the Compliance Department reported to the board on updates to the OIG's Guidance for Compliance Oversight by Health Care Boards.[50] The report explained what steps boards should take to engage in appropriate oversight of the compliance program and concluded that "Purdue's compliance program is regularly updated to account for regulatory guidance, including the Sentencing Guidelines, OIG's Compliance Guidance, and CIAs"; "[w]e have a robust risk assessment process"; and the "Purdue organization is well trained, sensitive to good compliance practices, and comfortable communicating with the Compliance department."[51] The Compliance Department had "no recommendations for altering practices as a result of this Guidance."[52]
- In 2016, the Compliance Department reported to PPI's board that Skadden had reviewed Purdue's Commercial Compliance Program in the fourth quarter of 2015 and had given it a "Positive review."[53] The Board was also told that Skadden concluded that "compliance controls are consistent with industry

[49] *Id*.

[50] *See* August 20, 2015 Quarterly Compliance Report (PPLP004412152) at -153.

[51] *Id*. at PPLP004412158-63.

[52] *Id*. at PPLP004412163.

[53] Quarterly Ethics & Compliance & Report to Board of Directors for 4Q2015 (March 10, 2016) (PPLP004412818) at -819.

practice and requirements established in recent Corporate Integrity Agreements between pharmaceutical manufacturers and OIG."[54]

- In 2017, the Ethics & Compliance Department reported to the board, once again, that "[w]e regularly evaluate our program against the OIG's 7 Elements of an Effective Compliance Program," and explained ongoing efforts to "maintain the highest ethical standards and continued compliance with all laws, regulations and Company policies."[55]

Accordingly, for the portion of the Relevant Period following the expiration of the CIA, no person familiar with corporate governance practices could in my opinion reasonably conclude in light of the foregoing information that the Former Directors "(a) … utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, consciously failed to monitor or oversee [Purdue's] operations thus disabling themselves from being informed of risks or problems requiring their attention."[56] To the contrary, during the period from the termination of the CIA through 2018, based on the information supplied by management and in light of the compliance system guidance from the HHS OIG and the U.S. Sentencing Guidelines, the Former Directors had ample bases to conclude, consistent with customary norms regarding the oversight responsibilities of corporate directors, that Purdue's program for assuring that OxyContin and other opioids were being marketed in a manner consistent with applicable law and regulations was meaningfully effective.

[54] 3Q 2016 Quarterly Compliance Report (PPLPUCC9002790025) at slide 3 (notes).

[55] *See* March 2017 Ethics & Compliance Report (PPLP004413913) at -916, -923.

[56] *Hughes*, 2020 WL 1987029, at *14; *Grika*, 2016 WL 8716417, at *16.

Diversion

38. With regard to diversion of opioids in the period after May 2007, I begin by noting that diversion of opioids has been a risk that PPI's board and Purdue management have recognized for a long time. I therefore review below the PPI directors' oversight of the system of controls and monitoring instituted and implemented by Purdue to address that risk.

39. During the Relevant Period, that system included a program known as the Abuse and Diversion Detection ("ADD") program that Purdue originally put in place in 2002. *See* SAF ¶¶166-79. The ADD program required all Purdue sales representatives and medical liaisons to submit an ADD report upon "learn[ing] of a circumstance or mak[ing] an observation that may be indicative of potential abuse or diversion."[57] The ADD Program specified objective triggers requiring a report, including atypical prescribing habits; excessive numbers of patients; credible allegations of diversion, abuse, or patient overdose; unauthorized signing or dispensing; and investigation by authorities.[58] Information obtained during sales calls was required to be reported through Purdue's call note system or to Drug Safety & Pharmacovigilance and was forwarded to the Law Department.[59] The Law Department investigated each ADD Report, following a

[57] June 15, 2007 ADD SOP 1.7.1 (PPLP003429997) at -997-99; Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -073-75; Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -429-31.

[58] June 15, 2007 ADD SOP 1.7.1 (PPLP003429997). Purdue added another two triggers to the ADD Program in 2015, in connection with the Assurance of Discontinuance Purdue entered into with the State of New York. *Compare* June 15, 2007 ADD SOP 1.7.1 (PPLP003429997) at 998-99 *with* September 2015 ADD SOP 1.7.1 (PPLP004035073) at 073-74.

[59] June 15, 2007 ADD SOP 1.7.1 (PPLP003429997) at -997-99; January 25, 2018 ADD Program Working Practices Document (PPLPC023000971903) at ¶5.C.

detailed set of procedures to determine whether to place the prescriber on the Company's No Call list, commonly referred to as Region Zero.[60] If the Law Department placed a prescriber in Region Zero, sales representatives were prohibited from calling on that prescriber and would not earn any sales incentive bonus based on prescriptions that prescriber wrote.[61]

40. There is a great deal more substance and detail to the ADD program and other measures that Purdue employed to detect and stem opioid abuse and diversion, but PPI's directors did not directly and personally participate in the administration of those activities; hence, the focus here is on how they monitored the operation of those activities:

- In its July 2007 report to the PPI board, management advised that in its agreements with various state Attorneys General, Purdue had made a "a number of commitments, including the issuance and training of certain personnel on Purdue's Abuse and Diversion Detection Program, which was required to be accomplished within 30 days of the judgment in the matter, and as to which a certification of Purdue's VP of Corporate Compliance was made June 20th."[62]
- After the ADD Program was incorporated into the requirements of the 2007 consent judgements with 26 states and the District of Columbia, Purdue's

[60] *See* Internal Inquiries: Procedures (PPLPC019000213919) ("In each instance in which the General Counsel's office receives notification of a sales representative's or other field personnel's concern about a healthcare professional's conduct that may indicate abuse or diversion of OxyContin or other controlled substances distributed by Purdue, the General Counsel's office will follow the procedures outlined below.").

[61] *See* June 15, 2007 ADD SOP 1.7.1 (PPLP003429997); September 2015 ADD SOP 1.7.1 (PPLP004035073); August 2017 ADD SOP 1.7.1 (PPLPC016000316429).

[62] Purdue Quarterly Report to the Board, July 15, 2007, at 53 (PPLP004366645) at -697.

management continually advised the Board over the next several years that Purdue was in full compliance with the Consent Judgments.[63]

- PPI's board was informed by management that each report generated through the ADD program was "subject to follow up by [the] Law Department."[64]
- PPI's board received regular updates on the types of issues that emerged through internal reporting sources governed by the ADD Program and ROC reporting, as well as through Purdue's call notes and hotline. The Compliance Department reported, for example, on the number of inquiries it received for investigation, how many related to abuse or diversion matters[65] and how long each quarter's inquiries took to close.[66]
- PPI's board was also apprised of the development and evaluation of Purdue's abuse deterrent formulation of OxyContin, first introduced following FDA approval in 2010. More specifically, the board was informed of studies based on third party data indicating that introduction of the abuse deterrent formulation resulted in significant reductions in abuse and diversion.[67] In November 2011, the

[63] *E.g.*, January 18, 2012 Board Compensation Committee Slides (PPLPC042000025057) at 28 ("Satisfied CIA and AG requirement for all … Abuse and Diversion Detection Reports").

[64] Attachment to Executive Committee Notes sent to the Board on October 25, 2011 (PURDUE-COR-0032186) at 3.

[65] *See, e.g.*, Corporate Compliance Quarterly Report to Board 2Q10 (July 22, 2010), at (PPLP004404551) at -564, - 566 ("134 'matters' in 2Q10," with just four related to ADD).

[66] *See, e.g.*, Corporate Compliance Quarterly Report to Board of Directors 1Q2010 (May 6, 2010) (PPLP004404102) at -115 (70 inquiries, including five involving abuse and diversion, resolved with 7 days, and all within 90 days).

[67] *See, e.g.*, Update on Purdue's Post-Marketing Epidemiology Studies of Reformulated OxyContin's Effects (June 18, 2012) (PPLPC057000011188) at -194, slides 9, 11 (reduction in diversion) and cover email conveying slides to PPI board members

board was informed that the chief of the Regulatory Section of the DEA's Office of Diversion Control had reported to Purdue executives that the reformulation "has made a tremendous difference" and "is saving lives," and that the DEA "[n]o longer hear[s] about OxyContin from field offices."[68]

- Following their meeting on July 22, 2010, PPI's board of directors raised with management the question of tracking Region Zero prescribers. In response, management informed the directors that prescription data is tracked and "the rate of no-call prescribers assigned to Region 0 is rising," potentially due to, among other things, enhanced data resources, enhanced training of representatives, and increased data auditing.[69]
- As PPI's board was informed, the New York Attorney General's investigation of Purdue's ADD program resulted in entry in 2015 of an Assurance of Discontinuance ("AOD"). That AOD, which provided for payment by Purdue of just $75,000 in "penalties, fees and/or costs,"[70] found that Purdue's "ADD Program can be an effective tool in identifying potential abuse and illegal diversion of opioids."[71] The AOD (at ¶28) required that Purdue maintain the ADD Program (with modest modifications) "for as long as Purdue promotes

(PPLPC057000011188); March 21, 2013 Board of Directors Meetings (U.S. Companies) / Agenda (PPLPC044000041897) at -961, -962, -968 (reduction in abuse).

[68] 2012 Budget Presentation, Legal Department, Government Investigations & Other Initiatives (November 2011) (PPLPUCC9011086649) at slide 6.

[69] Purdue Pharma Shareholders and Board Meeting, Questions Arising During the Presentations, July 22, 2010 (PPLPC012000283163) at -169-70.

[70] AOD ¶¶8, 38 (PPLP004035441) at -443, -457.

[71] *Id.* at ¶15. The AOD was the impetus for the addition of two reporting triggers to the 13 already specified in the ADD program. SAF ¶216.

OxyContin to [prescribers] through sales representatives."[72] The AOD also required that Purdue hire an independent, outside auditor approved by the New York AG to monitor and report for a period of three years on Purdue's compliance with its ADD Program and "the reasonableness of Purdue's decisions regarding whether to continue marketing or promoting opioid products to the [prescribers] at issue in each ADD Report."[73] During that three year period, and after reviewing all "continue to call" or "resume calling" determinations Purdue's Law Department made, the auditor reported that Purdue was implementing its ADD program "reasonabl[y]," "conscientiously and in good faith," and that Purdue was in compliance with the AOD.[74] He identified just **one** determination out of a total of 906—98 in 2016, 261 in 2017, and 547 in 2018—that, while made conscientiously and in good faith, he believed was not reasonable.[75]

[72] Indeed, in 2016, the New York Attorney General entered into an Assurance of Discontinuance with another manufacturer of oxycodone products, Endo, and it required that Endo adopt an ADD Program nearly identical to Purdue's. *In the Matter of Endo Solutions Inc. and Endo Pharm. Inc.*, Assurance No. 15-228 (Mar. 1, 2016) at 17-18.

[73] AOD at ¶41(b).

[74] October 7, 2016 Auditor's First Report on Purdue's ADD Program (PPLP004473667) at -668. *See* October 20, 2017 Auditor's Second Report on Purdue's ADD Program (PPLP004473709) at -710 ("the Company continues to operate the ADD Program in compliance with [the consent judgments]"); October 19, 2018 Auditor's Third Report on Purdue's ADD Program (PPLP004473738) at -740 ("the Company continued to operate the ADD Program in compliance with [the consent judgments]").

[75] October 7, 2016 Auditor's First Report on Purdue's ADD Program (PPLP004473667) at -668; October 20, 2017 Auditor's Second Report on Purdue's ADD Program at 3 (PPLP004473709) at 711; October 19, 2018 Auditor's Third Report on Purdue's ADD Program (PPLP004473738) at 740. With respect to the one determination the Auditor concluded was not reasonable, he reported that, because Purdue had ceased promoting opioids, the determination had become moot and, had it not been mooted, he would have recommended that Purdue revisit its determination "and based on prior experience thinks it likely that the Company would have revisted its position." *Id.* at 754.

41. In addition to the ADD progam, the PPI board also received other reports about programs implemented by Purdue to address and prevent diversion. For example:

- Purdue's management regularly reported to the board that the Risk Management & Health Policy Department was monitoring abuse and diversion of Purdue's opioid products, reviewing Reports of Concern ("ROCs") (*i.e.*, reports of "an alleged occurrence of misuse, abuse or diversion of a Purdue Marketed Opioid Analgesic"[76]) and conducting field inquiries.[77]
- Purdue implemented procedures to ensure that its employees reported any "[A]dverse Event ... occur[ring] during the course of the drug's use in professional practice, as well as from … [a] drug overdose, whether accidental or intentional[, d]rug abuse, [or] [d]rug withdrawal,"[78] and, in a compliance report slide deck presented in 2008, management explained to the PPI board, under the heading "Sales Force Monitoring," that "[a]dverse events, product complaints,

[76] 2008 Training Materials (PPLP003550586) at -624; Sept. 13, 2006 RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel (PPLPC039000340008) at §§2.3, 3.

[77] *E.g.*, Quarterly Report to the Board (April 15, 2008) (PPLP004367134) at-149-50 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "853 ROCs regarding abuse and diversion of PPLP's marketed opioid analgesics" and conducted "17 field inquiries ... in response to signals of abuse or diversion of OxyContin as identified via review of ROCs, and RADARS® System data").

[78] 2008 Training Materials (PPLP003550586) at -594. *See also* Mar. 15, 2005 MA-DSP-SOP-000001 (PPLPUCC002500202) at ¶3 (defining "Adverse Event" as "[a]ny adverse event associated with the use of a drug (or biological product) in humans, whether or not considered drug/product related," including "in the course of the use of a drug/product in professional practice," "from drug overdose whether accidental or intentional," "from drug abuse," "from drug withdrawal," and "any failure of expected pharmacological action").

[i]ndications of abuse or diversion [are] recorded in call system and automatically sent to Drug Safety & Pharmacovigilance Department."[79]

42. In light of the foregoing information, it is my opinion that no person familiar with corporate governance practices could reasonably conclude that, during the Relevant Period, the Former Directors "(a) … utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, consciously failed to monitor or oversee [Purdue's] operations thus disabling themselves from being informed of risks or problems requiring their attention,"[80] as far as addressing the risk of abuse and diversion of Purdue's opioid products was concerned. To the contrary, it is my opinion that the conduct of the Former Directors in regard to oversight of potential diversion of opioids, including OxyContin, satisfied or exceeded what the then-prevailing norms and custom and practice of corporate directors in that regard contemplated. There can be no dispute that the Former Directors knew that Purdue had implemented a vigorous abuse and diversion detection program and other anti-diversion measures to address diversion, that the ADD and other anti-diversion programs were in operation and taking concrete steps, including identifying and suspending marketing to Region Zero prescribers, and that the PPI board was receiving regular reporting about that program that repeatedly indicated that Purdue's ADD program was being conscientiously implemented.

[79] Corporate Compliance Quarterly Report to the Board of Directors, 3Q 2008 (Nov. 4, 2008) (PPLP004402032) at -086. *See also* Corporate Compliance Quarterly Compliance Report to the Board of Directors, 2Q 2011 (July 21, 2011) (PPLP004406466) at -485 (reporting that the sales force was monitored for "Adverse Event Reporting").

[80] *Hughes*, 2020 WL 1987029, at *14; *Grika*, 2016 WL 8716417, at *16.

Evaluation of Claims that the Former Directors or any other Raymond Sackler Family Members Directly Participated in Alleged Wrongful Activities

43. One of the core allegations against the Raymond Sackler family is that Former Directors participated directly in Purdue's allegedly deceptive or otherwise wrongful marketing of opioids. During the Relevant Period, however, with the exception of one family member who worked at Purdue part time for four months,[81] none of the Former Directors, nor any other members of the Raymond Sackler family, served as officers or employees of Purdue. Thus, the Former Directors and other members of the Raymond Sackler family did not conduct Purdue's business in any formal sense.

44. Claims of direct participation by the Former Directors therefore rest on two somewhat distinct categories of information: (a) documents suggesting that one or more of the Former Directors "micromanaged" Purdue's affairs generally (thereby supposedly implying that they must have each been personally responsible for directing any and all misconduct by Purdue); and (b) isolated communications with Former Directors generally involving inquiries or suggestions about sales performance or business plans. As discussed more fully below, neither category demonstrates conduct outside the scope of the normal range of responsibilities and activities of a director of a large corporation.

[81] Marianna Sackler worked for about four months in 2009-2010 at a part time job in Purdue's medical research and development department. Marianna Sackler Dep. at 30-33, 39. I have not encountered any allegation, including in the one complaint that I am aware of which names her as a defendant (First Amended Complaint, *People of California v. Purdue Pharma L.P., et al.*, Case No. 19STC19045 (Cal. Super. Ct. Los Angeles Cnty. Oct. 2, 2019)), that specifies how she participated in any wrongdoing in connection with that work.

"Micromanagement"

45. The first category described in the preceding paragraph involves assertions that certain of the Former Directors "micromanaged" Purdue, in the sense that they engaged in Purdue's affairs in a manner that exceeded the scope of their duties as directors and inappropriately intruded on the authority of Purdue's officers and management generally. These assertions suffer from two distinct shortcomings, however, as support for claims that the Former Directors should be held personally responsible for any harm resulting from marketing or diversion of OxyContin. First, as set forth in the SAF at ¶¶292-324 and not separately addressed in this report—the cited evidence of supposed "micromanagement" does not establish any involvement by the Former Directors in the improper marketing of OxyContin by Purdue or failure by the PPI board to devote sufficient attention to oversight of marketing and diversion of OxyContin. Second, and as reviewed below, the conduct of the Former Directors was, in my opinion, appropriate engagement, and not more active or intrusive upon management than what is expected from directors of a large, privately held company like Purdue in light of customary norms concerning the roles and practices of corporate directors.

46. Before reviewing illustrative specific instances of claimed "micromanagement," it is helpful to identify some of the customary norms of board practices as they existed during the Relevant Period. Those norms included the following propositions, all of which demonstrate that the role of the director is active, not passive:

- A director's functions include "monitoring the corporation's performance in light of its operating, financial, and other significant corporate plans,

strategies, and objectives."[82]

- "Because of important business decision and oversight responsibilities, all directors have both legal and customary rights of access to the information and resources needed to do the job[, including] the rights: … to inspect books and records; to request additional information reasonably necessary to exercise informed oversight and make careful decisions; [and] to inspect facilities as reasonably appropriate to gain an understanding of corporate operations."[83]
- "[A] director's understanding of the corporation and its industry should include … the key drivers underlying the corporation's profitability and cash flow—how the corporation makes money both as a whole and also in its significant business segments … ."[84]
- "Directors are expected to use their knowledge, experience, and special expertise for the benefit of all directors and the corporation generally."[85]
- "If a director believes that information [received from management] is insufficient or inaccurate, or is not made available in a timely manner, the

[82] *Corporate Director's Guidebook*, 66 BUS. LAW. at 986; ALI PRINCIPLES, § 3.02(a)(2) ("The board of directors of a publicly held corporation … should … [o]versee the conduct of the corporation's business to evaluate whether the business is being properly managed….").

[83] *Corporate Director's Guidebook*, 66 BUS. LAW. at 988-89; *see also* ALI PRINCIPLES § 3.03(a) ("Every director has the right … to inspect and copy all books, records, and documents of every kind, and to inspect the physical properties, of the corporation and of its subsidiaries, domestic or foreign, at any reasonable time, in person or by an attorney or other agent.").

[84] Corporate Director's Guidebook, 66 BUS. LAW at 987.

[85] *Id.* at *991*.

director should request that action be delayed until appropriate information is available and can be studied."[86]

- "[D]irectors should have an attitude of constructive skepticism. Directors should not be reticent or passive. To be a director means to direct—to participate on an informed basis, ask questions, challenge management as appropriate, apply considered business judgment to matters brought before the board, and when necessary, bring other matters to the full board's attention."[87]

47. In some respects, conformity with these norms results in tension between directors and management, because they encourage directors to "challenge" management with "skepticism," to seek information beyond what management has provided, and to act on the basis of their own experience and expertise, especially where such action calls into question assertions or judgments presented by management. Thus, what management may openly criticize and resent as intrusive may often be the result of directors acting in accordance with the norms of director conduct as outlined above.[88] Indeed, a complete absence of tension between directors and management may suggest that directors are behaving passively and failing to fulfill the full scope of their customary roles and responsibilities as directors.

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[86] *Id.*

[87] *Id.* at 988.

[88] *See* 1 KNEPPER & BAILEY, *supra* footnote 11, "§ 1.03 ("The oversight function of a board of directors at times creates friction between the board and management with respect to the appropriate degree to which the board becomes involved in management activities.").

48. The foregoing recitation of customary norms and practices of corporate directors draws heavily from experience with large corporations with publicly traded shares, in which typically a large majority of the members of the board of directors are not, and have never been, officers of the corporation. Reference to those norms and practices is therefore appropriate in assessing the conduct of the Former Directors during the Relevant Period, when none of them was a senior corporate officer. Nevertheless, given the norm that "directors are expected to use their knowledge, experience, and special expertise for the benefit of all directors and the corporation generally,"[89] any Former Directors with significant direct managerial experience with Purdue before the Relevant Period would appropriately be expected to question management more thoroughly and participate more actively in board meetings than a director lacking such knowledge and experience.

49. With the foregoing exposition of the roles and responsibilities of directors in mind, I turn to an assessment of some of the evidence cited for the assertion that one or more Former Directors "micromanaged" Purdue:

- One statement that has figured prominently in this regard is in a document prepared in 2017 by Dr. Craig Landau, concerning "global investment strategy," and indicating that "the Board of Directors [has been] serving as the 'de-facto' CEO."[90] It appears from the document itself and from Dr. Landau's testimony, however, the quoted statement has nothing to do with Purdue or PPI but rather with the Sackler families' global pharmaceutical

[89] *See* footnote 86 above.

[90] PWG004670879 (May 5, 2017 email from Craig Landau to Mortimer Sackler) at -880.

operations. At the time he prepared the document, Dr. Landau was an officer not of Purdue or PPI, but of Purdue's Canada affiliate, and it was his intent that the document be presented not to PPI or its board, but to the board of MNP Consulting, Limited ("MNP"), which was advising 49 companies outside the U.S.[91] Based on that testimony, I have not considered the document relevant to the question of whether Former Directors acted in accordance with customary norms of board practice with respect to PPI.

- Other "micromanagement" assertions have similarly and inappropriately conflated MNP with PPI and are not relevant to my analysis for the same reason. Thus, for example, a 2011 memorandum stating "the role of the board and that of the management is blurred compared with the distinctions made by other major corporations" actually refers to the MNP board, not the board of PPI.[92] Similarly, the statement in a 2015 email exchange that a draft resolution was prepared to stop certain directors from "bombarding execs with ... ideas and trying to influence them"[93] refers to the MNP board, as reflected by Kathe Sackler's testimony.[94]

[91] Landau Dep. Tr. at 329-330. *See also* SAF ¶¶50-54.

[92] Nov. 18, 2020 Unsecured Creditors Committee Reply (ECF No. 2164) at ¶30, quoting PPLPUCC9003800123 (February 15, 2011 email from Jonathan Sackler) (the memorandum references considering "a global CFO and/or a global strategy executive," discusses its "geographic regions," and notes that the "Board" should consider adopting committees with a "global remit.").

[93] Nov. 18, 2020 Unsecured Creditors Committee Reply (ECF No. 2164) at ¶31, citing PPLPUCC9004448656 (June 20, 2015 email chain between Theresa Sackler and Mortimer D.A. Sackler).

[94] SAF ¶305.

More importantly, criticizing directors when they present "ideas" to executives and "try[ ] to influence them" inappropriately minimizes the role of the board, which includes the widely recognized responsibility to "provide general direction and guidance with respect to the corporation's strategy and management's conduct of the business."[95] In the 2015 email exchange, Mortimer Sackler, Jr.'s response was thus correct: disagreeing with the assertion that directors could convey questions and issues to corporate officers, but should not convey a "point of view," he responded that the executives "need to understand where the Board and its individual members stand in order to better/more successfully do their jobs and bring proposals forward that are likely to pass the Board and not get shot down."[96]

- Finally, it has been claimed that a non-Sackler family board member (Cecil Pickett) "acknowledged that Board members continued inappropriately to 'get in the weeds' of Purdue's affairs."[97] The use of the word "inappropriately" should be tested against Mr. Pickett's actual testimony:

> Q Were there also disagreements at board meetings about operations of the company that you viewed were really operational issues that should be left to management? …
>
> THE WITNESS: You know, you know, I think some members of the board got a little more granular than other members when

[95] Corporate Director's Guidebook, 66 BUS. LAW. at 986.

[96] PPLPUCC9004448656 (June 20, 2015 email chain between Theresa Sackler and Mortimer D.A. Sackler).

[97] Nov. 18, 2020 Unsecured Creditors Committee Reply (ECF No. 2164) at ¶31.

> certain issues or certain management presentations came up. **I didn't view that as necessarily unusual because I had seen it at other boards.** You know, some board members want to know all the nuts and bolts of things.· I probably could have been accused of that myself in terms of some of the R&D programs, about maybe getting a little too granular. So I didn't -- **I didn't see it in terms of overseeing or being -- being part of management**.[98]
>
> Q And **was that a concern that the non-Sackler directors had about the board involvement; that there was not a clear separation of management and board responsibilities?**
>
> A **No, I don't think so**. I think probably this sentence came because of perhaps some of Richard's behavior about being just -- just so granular in terms of board meetings.[99]

In short, Mr. Pickett's testimony confirms that however "granular" any of the Former Directors may have gotten in board meetings, their behavior was consistent with behavior that Mr. Pickett had observed in other boards of directors, and did not overstep any line between management and board responsibilities.

Inquiries and Suggestions About Sales and Marketing

50. Apart from assertions of generalized "micromanagement," there have been claims that one or more Former Directors directly and personally participated in improper promotion of the sale of OxyContin. No evidence has come to my attention, however, of any communication by a Former Director making or approving any false, misleading, or otherwise improper promotion of opioid sales by Purdue. Assertions of liability of Former Directors have focused instead on what directors may have done to encourage management to increase sales of OxyContin in order to increase profitability.

[98] Pickett Dep. Tr. at 143:10-144:14 (emphasis added).

[99] Pickett Dep. Tr. at 147:5-14 (emphasis added).

Encouraging management to increase sales and profitability through legal means, however, does not constitute a breach of a director's fiduciary duty; to the contrary, it is conventionally accepted among practitioners of corporate governance that seeking to promote shareholder profit in compliance with the law is the core purpose of the corporation and its board of directors.[100] Directors are of course not permitted to cause a corporation to seek profit by illegal means, but during the Relevant Period, OxyContin, while closely regulated, was (and remains today) an FDA-approved medication that is available only with a prescription; indeed, the FDA, a principal regulator, stated publicly when it approved Purdue's abuse deterrent labeling of OxyContin in 2013 that it "remains committed to ensuring that patients with pain have appropriate access to opioid analgesics."[101] In these circumstances, therefore, and in the absence of proof that the directors consciously disregarded legal limitations or risks associated with OxyContin (*see* paragraphs 30-42 above), efforts by such directors to explore and encourage development of additional opportunities to promote the legal sale of OxyContin were consistent with both the law and prevailing norms of director conduct. In that light, as reflected in the examples reviewed below, conduct by certain of the Former Directors that has been characterized as improper appears, to the contrary, to have been both legal and commensurate with customary norms and practices of corporate directors:

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[100] *Corporate Director's Guidebook*, 66 BUS. LAW. at 985 (directors "must focus on maximizing the value of the corporation for the benefit of its shareholders.").

[101] "FDA approves abuse-deterrent labeling for reformulated OxyContin," FDA News Release (Apr. 16, 2013), available at https://wayback.archive-it.org/7993/20170112223041/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm.

- In 2008, Richard Sackler suggested revisions to sales projections initially presented by management, and this is cited as an "intervention[] with Purdue's nominal executive team to drive increased sales."[102] Far from being improper, however, this sort of input was a natural manifestation of the norm noted above that "directors are expected to use their knowledge, experience, and special expertise for the benefit of all directors and the corporation generally."[103] Richard Sackler would have been remiss in his role as a director had he (a) failed to scrutinize an important forecast presented by management or (b) having scrutinized it, failed to challenge management if he felt, based on his own knowledge and experience, that the forecast should be improved. Indeed, the upshot of Richard Sackler's involvement in this particular forecast was management's conclusion that the exercise was "helpful from the perspective of helping expand Richard's knowledge of the analyses and considerations that have already gone into the 2008 OxyContin forecast."[104]
- In 2009, Richard Sackler announced a meeting of the board and staff to hear a presentation about "'all the efforts Sales and Marketing is doing and planning to do to reverse the decline in [the] OxyContin tablets market," and he noted that profit from incremental sales could be $200 million.[105] This effort to examine sales and marketing efforts was consistent with the norms recited above that a

[102] Nov. 18, 2020 Unsecured Creditors Committee Reply (ECF No. 2164) at ¶34.

[103] *See* footnote 86 above.

[104] March 10, 2008 email chain between John Stewart, David Rosen and others (PPLPC012000174476).

[105] August 12, 2009 email from Richard Sackler (PPLPC012000234970) at -970.

director's functions include "monitoring the corporation's performance in light of its operating, financial, and other significant corporate plans, strategies, and objectives,"[106] and that "a director's understanding of the corporation and its industry should include … the key drivers underlying the corporation's profitability and cash flow—how the corporation makes money both as a whole and also in its significant business segments."[107]

- Similarly, in late 2009 Richard Sackler and another PPI director (Kathe Sackler) requested information about several matters: the market for certain opioids; growth rate for purposes of projections; sales and marketing programs to be implemented to respond to competitive threats; whether "share of voice" could increase sales and profit; and a copy of a McKinsey report about ways to increase OxyContin sales and market share.[108] These are requests for high level information about business plans and strategies, not direction of detailed marketing efforts. Accordingly, the requests are consistent with the norm noted above that "[b]ecause of important business decision and oversight responsibilities, all directors have both legal and customary rights of access to the information and resources needed to do the job, [including] the rights: … to inspect books and records; to request additional information reasonably necessary to exercise informed oversight and make careful decisions; [and] to inspect

[106] Corporate Director's Guidebook, 66 BUS. LAW. at 986.

[107] *Id.* at 987.

[108] PPLPC012000245368 (Notes and Actions from 2010 Budget Presentation on November 2nd and 3rd 2009).

facilities as reasonably appropriate to gain an understanding of corporate operations."[109]

- This customary right "to inspect facilities as reasonably appropriate to gain an understanding of corporate operations" places Richard Sackler's request in 2011 to accompany Purdue sales representatives into the field to visit prescribers[110]—and the one field visit he eventually took with one sales representative, *see* SAF ¶307—squarely within the field of normal conduct of a corporate director.[111] Dr. Sackler's observation of the activities and follow up questions to management were entirely consistent with responsible diligence of a corporate director, and did not cross a line into management of the company's marketing operations.

51. It has been asserted that the Former Directors crossed that line in 2013 by promoting a plan (known as the "E2E" project) to "turbocharge" Purdue's sales of OxyContin, by targeting the most active prescribers.[112] However, the E2E program was

[109] Corporate Director's Guidebook, 66 BUS. LAW. at 988-89.

[110] PPLPUCC9000363533 (May 3, 2011 email from John Stewart to Richard Sackler). It bears noting that this information-gathering exercise focused on Butrans, an opioid patch which at the time was a new product, and not on OxyContin.

[111] Jonathan Kim and Marcel Bucsescu, *Greater Expectations: Strategies for Effective Board Meeting Preparation* (2018) at 2-3, *available at* https://millstein.law.columbia.edu/sites/default/files/content/images/5943_millstein_center_director_papers_-_greater_expectations.pdf.pdf ("Directors should also make efforts to better understand the company's operations outside of the board setting. This is important not just for their own grasp of the organization and its culture, but also as a way to hear different perspectives on the company's products or services. For example, as a director, if your company manufacture[]s vehicles, make a casual visit to a dealership to see how products are marketed directly to the consumer; as a director of a bank, open a new account or meet with a teller to assess the customer service and process.").

[112] *E.g.*, Nov. 18, 2020 Non-Consenting States' Statement (ECF No. 2012), at ¶¶ 21-24; MCK-MAAG-0112708 (Feiner Decl. Exhibit L), MCK-MAAG-0112331 (Feiner Decl. Exhibit O), and MCK-MAAG-0119088 (Feiner Decl. Exhibit P).

not initiated or even specifically approved by the Former Directors. *See generally* SAF ¶¶272-91. E2E—including the use of the word "turbocharge"—was an approach devised by McKinsey & Company, which was retained by Purdue management in May 2013, without prior consultation with the board;[113] after the approach was first presented to the PPI board in August 2013, an internal McKinsey email recited that the "Board had not engaged on our work" (and in particular, "Dr. Richard [Sackler] had not read [our] memo.").[114] After the board did engage more fully, its input at its meeting in October 2013 cautioned against a single-minded focus on increasing sales: notes from that meeting reflect board advice that "[i]n terms of incentives, the salesforce (and indeed the entire organization) should be driven to be of high value to patients and physicians (and the healthcare system), and not simply to increase prescriptions for Purdue products."[115] Most importantly, the Former Directors had ample reason to believe that the E2E project would serve the proper purpose of promoting the pursuit of legitimate profit: it was developed and proposed by McKinsey, then a widely respected consulting firm;[116]

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[113] PPLPC051000178707 (statement of services "effective as of May 28, 2013"); PPLPC012000424137 (May 19, 2013 email from David Rosen to Russell Gasdia and Michael Ronning) at -137, PPLPC057000014144 (June 5, 2013 email from Edward Mahony) at -145 ("McKinsey has been engaged to work with Sales & Marketing to identify opportunities to improve performance of OxyContin."). I do not mean to imply that there was anything improper about the fact that management retained McKinsey without consulting the board, especially because the scope of the E2E project was relatively small, contemplating an "upside" of about $100 million in sales, as compared to Purdue's overall sales of over $2 billion. PPLP004409890 (August 15, 2013 Board Agenda) at -892; PPLP004409973 (November 2013 Budget Book) at -988.

[114] Nov. 18, 2020 Non-Consenting States' Statement (ECF No. 2012); MCK-MAAG-0112331 (Feiner Decl. Exh. O).

[115] PPLPC012000452389 (November 18, 2013 email from John Stewart) at -392.

[116] *See Samaritan Inns v. District of Columbia*, 1995 WL 405710, at *6 (D.D.C. June 30, 1995), *rev'd in part on other grounds*, 114 F.3d 1227 (D.C. Cir. 1997) (referring to McKinsey as "an internationally respected consulting firm"); *Mercier v. Inter-Tel (Del.)*,

McKinsey advised that the focus on "higher value prescribers" reflected "[b]est practice in the industry;"[117] the board had been given specific and repeated assurances about the efficacy of Purdue's anti-diversion program (see SAF ¶¶154-163); it was specifically informed that oversight of the E2E project would include participation by the senior legal and compliance officers;[118] and the board was aware that Purdue's relatively new abuse deterrent formulation of OxyContin had the potential to expand Purdue's share of the legitimate market for prescription analgesics at the expense of its competition, and that there was therefore nothing inherently suspect about a program to expand sales of that formulation.[119] In sum, the PPI board's engagement with information about the implementation of the management-driven E2E project was consistent with both applicable law and customary norms of director conduct, both of which contemplate and validate good faith reliance on advice and recommendations by management and by expert advisors like McKinsey.[120]

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Inc., 929 A.2d 786, 799 (Del. Ch. 2007) ("the respected firm of McKinsey & Co").

[117] PPLP004409890 (August 15, 2013 Board Agenda) at -892.

[118] PPLP004409973 (November 2013 Budget Book) at -10022.

[119] *E.g.*, October 2012 sales and marketing presentation (PPLPC012000396110) at slide 8; November 2014 Budget Presentation (PPLP004411368) at -412 (emphasizing the "importance of abuse deterrence as a key driver for ERO [extended release opioids] prescribing").

[120] N.Y. B.C.L. § 717(a); *Corporate Director's Guidebook*, 66 BUS. LAW. at 991 ("Obtaining input from competent advisors is a hallmark of a careful decision-making process. For this reason, directors who rely in good faith on advisors, professionals, and other persons with particular expertise or competence generally enjoy broad protections from liability.").

52. Based on the information and analysis set forth above, it is my opinion that the conduct of the Former Directors during the Relevant Period did not amount to personal, direct participation in any wrongdoing by Purdue, and was consistent with then prevailing norms and custom regarding the appropriate role of corporate directors.

Exercise of Control Through Ownership or Control of PPI Shares

53. As a matter of both case law and common practice and understanding among practitioners and planners of corporate governance arrangements, a person who has the right to vote sufficient shares of stock to elect a majority of the directors of a corporation is considered to have effective control of the corporation. Conversely, a person who does not have that right is not considered to have effective control of the corporation, unless that person has exercised actual domination and control over his or her fellow directors by use of a power that deprived the other directors of their ability to freely exercise their judgment. Without that power, and its actual use, no person can be said to control the collective will of the board of directors and thereby control the corporation. Indeed, control through ownership and voting of stock sufficient to remove and elect the board of directors is common in parent/subsidiary relationships, and especially because it is common practice it is insufficient, standing alone, to warrant making the holder of such control liable for the obligations of the corporation.

54. In any event, judging by the facts I have reviewed, none of the Former Directors or any other members of the Raymond Sackler family had that power, let alone exercised it. First, none of those individuals directly owned any shares of PPI stock: shares of Class B stock of PPI were held by trusts of which none of the Raymond Sackler family members was either the trustee or a beneficiary. And even if those individuals had

owned PPI shares directly, under the terms of PPI's articles of incorporation they had no power, even as a group, to cause PPI's board of directors to take (or refrain from taking) action, because no board action could be taken unless a majority of each of the two classes of directors approved of it, and no individual director had the power to prevent the board from taking action, as long as a majority of both classes of directors approved of the action.[121] Thus, none of those persons, even in combination with the other members of the Raymond Sackler family, was in a position through share ownership to impose their will on the directors elected by the holders of the Class A stock of PPI. Put more directly, none of the members of the Raymond Sackler family had the power to control PPI's board of directors, and thereby control PPI.[122]

55. It cannot be assumed, moreover, that the members of the Mortimer Sackler family who indirectly elected the Class A directors and the members of the Raymond Sackler family who indirectly elected the Class B directors acted in lockstep unison, or even that the members of either group behaved in monolithic fashion in regard to actions subject to the authority of PPI's board of directors. To the contrary, there is evidence that they did not. For example:

- In a May 2009 email exchange, Richard Sackler (Side B) suggested to Mortimer Sackler, Jr. (Side A) the possibility of acquiring a business (Remoxy) at its cash

[121] And as noted in the next paragraph, it cannot be assumed that the members of either class of directors acted monolithically in approving or opposing board action, and there is evidence that they did not.

[122] The same proposition applies to PPLP: none of the members of the Raymond Sackler family had the power to control PPLP, given that they held no limited partnership interest in PPLP directly, and that PPI, as general partner, maintained general managerial power over PPLP. *See* footnote 17 above. I have encountered no evidence, moreover, that any of the members of the Raymond Sackler family even purported to invoke any indirect limited partnership interest in PPLP in attempting to participate in the business of PPLP.

value. The response to that suggestion was decidedly negative, and, recognizing that it would be impossible to proceed with the acquisition without the consent of a majority of the Class A directors, Richard Sackler replied "I see your point of view. Maybe I don't agree, but I see it. Enough said about this." [123]

- Five years later, in October 2014, an email from David Sackler refers to a refusal to approve pursuit of an acquisition of a company named Igenica, and states that "[t]he Mortimer family's refusal to take on that project was horrible, their bizarre bureaucratic behavior afterwards is almost as bad."[124]
- That same incident also highlighted tension between the Side A and Side B family members with respect to the desirability of distributions to shareholders. David Sackler's email noted "Mortimer Sackler's hutzpah in even thinking about distributions after the Igenica discussion," and Jonathan Sackler soon thereafter described the Side B members' preference for leaving "cash on the balance sheet" with a view to creating "long-term wealth," as opposed to the Side A members' more "activist hedge fund playbook as practiced by people like Carl Icahn ... [which] typically involves pulling cash out of operations."[125] A June 2015 email again reflected these competing philosophies, reciting that Side B urged that "cash distributions ... be tempered," and expressed their desire to have "the lowest acceptable amount of cash coming out of the company."[126]

[123] PPLPC061000042437.

[124] PPLPUCC002907060.

[125] PPLPC045000017193 (November 15, 2014 email from J. Sackler) at -194.

[126] RSF_OLK00021303 (June 28, 2015 email from S. Ives) at -305, -306.

Nor could it be assumed that members of even the same side of the family would make decisions in lockstep. Thus, for example, in 2016 the PPI board was split regarding a proposed deal involving Exicure, and so were the Side B directors, with Jonathan Sackler and David Sackler voting in favor and Richard Sackler opposed.[127] Similarly, in 2014 the PPI boad was split regarding a proposed acquisition of Rye Pharmaceuticals, and so were the Side B directors, with Richard Sackler and David Sackler voting in favor and Jonathan Sackler opposed.[128]

56. The foregoing examples contradict any claim that the members of the Raymond Sackler family, even if they were to have acted in unison on all Purdue-related matters, exercised effective control over PPI's board of directors. It should be noted, of course, that even if, by virtue of share ownership or otherwise, a member of the Raymond Sackler family did have the power to control PPI's board of directors, that level of control would not as a matter of law or practice render that director legally responsible for PPI's actions. To the contrary, in the absence of direct personal involvement in the conduct in question, attributing liability for corporate conduct to a controlling shareholder requires what is widely known as "piercing the corporate veil." There are compelling policy reasons, as referred to in paragraph 22 above, for extreme reluctance to attribute corporate conduct to controlling shareholders.

57. The members of the Raymond Sackler family, in their role as indirect beneficial owners of PPI shares, did not exceed the scope of activities that norms of corporate governance contemplated for corporate shareholders.[129] By seeking and

[127] Notes of October 2016 PPI Board meeting (PPLPBN-00002815) at -834.

[128] Notes of October 2014 PPI Board meeting (PPLPBN-00002063) at -2090.

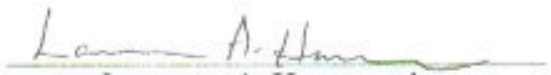
[129] Similarly, to the extent that members of the Raymond Sackler family were indirect

obtaining representation on the corporation's board of directors, communicating with members of the board of directors (including members whom they nominated or designated to serve on the board) concerning the corporation's performance and business plans, and seeking and obtaining information from the corporation concerning such performance and business plans, the members of the Raymond Sackler family engaged in no conduct that in my opinion would be considered to have been inconsistent with customary norms of corporate governance practices. In my opinion, it is impossible to conclude that PPI was "so dominated by an[y member of the Raymon Sackler family] …, and its separate identity so disregarded, that it primarily transacted the dominator's business rather than its own and can be called the other's alter ego."[130]

58. For the foregoing reasons, it is my opinion that none of the members of the Raymond Sackler family exercised control over PPI or Purdue by reason of ownership or control of shares of stock of PPI, and that under prevailing corporate governance standards they would not be held responsible for actions of PPI or Purdue in the absence of direct, personal involvement in corporate conduct.

beneficial owners of limited partnership interests in PPLP, I have not encountered any evidence that they exceeded the scope of activities that norms of governance of limited partnerships contemplated for limited partners.

[130] *See* footnote 13 above, quoting *Gartner*, 607 F.2d at 586.



Lawrence A. Hamermesh

DATE: Corrected as of July 12, 2021

EXHIBIT A TO THE EXPERT REPORT OF LAWRENCE HAMERMESH

LAWRENCE A. HAMERMESH

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EDUCATION AND CAREER HISTORY:

Admitted to the Delaware Bar, 1976; United States Supreme Court, 1999

Professor Emeritus (formerly Ruby R. Vale Professor of Corporate and Business Law), Widener University School of Law

- Teaching areas: business organizations, corporate finance, securities regulation, mergers and acquisitions, professional responsibility, equity/equitable remedies
- Director, Widener Law School Institute of Delaware Corporate and Business Law, 2000-2017
- Adviser, Delaware Journal of Corporate Law

Executive Director, University of Pennsylvania Law School Institute for Law and Economics, July 2016-present

Senior Special Counsel, Office of Chief Counsel of the Division of Corporation Finance of the U.S. Securities and Exchange Commission, Washington, D.C., January 2010 to June 2011

- Advising the Staff of the Commission on matters of state corporate law pertinent to the regulatory functions of the Commission

Visiting Professor, University of Michigan Law School, Winter 2002
Visiting Professor, University of Pennsylvania Law School, Spring 2004, Spring 2006, Spring 2014
Adjunct Professor of Law, New York University Law School, Fall 2008

Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware

- Associate, 1976-1984
- Partner, 1985-1994

Yale Law School – J.D., 1976

Haverford College – B.A., 1973

Other Professional Qualifications and Background Information:

Member, American Law Institute (elected 1999)
Adviser, Restatement of the Law, Corporate Governance (appointed March 2019)

Member, Council of the Corporation Law Section of the Delaware State Bar Association, 1995 to present; Vice Chair, 2000-2002; Chair, 2002-2004

American Bar Association Business Law Section:

Member, Section Council, 2009 – 2012

Corporate Laws Committee: Reporter, 2013 – 2020; Associate Reporter, 2011-2012; member, 2001-2007

Editorial Advisory Board, The Business Lawyer (2005-2017)

Chair, Corporate Documents and Process Committee, 2007-2010

Reporter, ABA Task Force on Corporate Responsibility (2002-2003)

2004 Daniel L. Herrmann Professional Conduct Award, Delaware State Bar Association

2006 and 2013 Douglas E. Ray Excellence in Faculty Scholarship Award

Secretary, Delaware Board of Bar Examiners, 1983-1987

Treasurer, Delaware Volunteer Legal Services, Inc., 1991-2000
Chairman, Lawyer Referral Service Committee of the Delaware State Bar Association, 1993-1998

PUBLISHED WRITINGS (partial list, including all publications within the last 10 years as of June 2021)

A Babe in the Woods: An Essay on Kirby Lumber *and the Evolution of Corporate Law*, 45 Delaware Journal of Corporate Law 125 (2020)

Delaware Corporate Fiduciary Law: Searching for the Optimal Balance, in EVAN J. CRIDDLE, PAUL B. MILLER, AND ROBERT H. SITKOFF, EDS., OXFORD HANDBOOK OF FIDUCIARY LAW (Oxford Univ. Press 2019) (with Leo E. Strine, Jr.)

The Role of Directors in M&A Transactions: A Governance Handbook for Directors, Management and Advisors, American Bar Association Business Law Section, published April 2019 (co-editor)

Finding the Right Balance in Appraisal Litigation: Deal Price, Deal Process, and Synergies (with Michael Wachter), 73 Business Lawyer 961 (2018)

Forum Shopping in the Bargain Aisle: Wal-Mart and the Role of Adequacy of Representation, in RESEARCH HANDBOOK ON REPRESENTATIVE SHAREHOLDER LITIGATION, SEAN GRIFFITH, JESSICA ERICKSON, DAVID H. WEBBER, AND VERITY WINSHIP, EDS. (Edward Elgar 2018) (with Jacob J. Fedechko)

Lyman Johnson's Invaluable Contribution to Delaware Corporate Jurisprudence, 74 Washington & Lee Law Review 909 (2017) (with Jack B. Jacobs)

The Importance of Being Dismissive: The Efficiency Role of Pleading Stage Evaluation of Shareholder Litigation, 42 Journal of Corporation Law 597 (2017) (with Michael Wachter)

A Most Adequate Response to Excessive Shareholder Litigation, 45 Hofstra Law Review 147 (2016)

Consent in Corporate Law, 70 Business Lawyer 161 (Winter 2014/2015)

How Long Do We Have to Play the "Great Game?," 100 Iowa Law Review Bulletin 31 (2015)

M&A Under Delaware's Public Benefit Corporation Statute: A Hypothetical Tour, 4 Harvard Business Law Review 255 (2014) (with Frederick Alexander, Frank Martin and Norman Monhait)

Director Nominations, 39 Delaware Journal of Corporate Law 117 (2014)

Putting Stockholders First, Not the First-Filed Complaint, 69 Business Lawyer 1 (2013) (with Leo E. Strine, Jr. and Matthew Jennejohn)

Who Let You Into the House?, 2012 Wisconsin Law Review 359 (2012)

Delaware Corporate Law and the Model Business Corporation Act: A Study in Symbiosis, 74 Duke Journal of Law and Contemporary Problems 107 (2011) (with Leo E. Strine, Jr. and Jeffrey M. Gorris)

Loyalty's Core Demand: The Defining Role of Good Faith in Corporation Law, 98 Georgetown Law Journal 629 (2010) (with Leo E. Strine, Jr., R. Franklin Balotti, and Jeffrey M. Gorris)

Rationalizing Appraisal Standards in Compulsory Buyouts, 50 Boston College Law Review 1021 (2009) (with Michael Wachter)

The Short and Puzzling Life of the "Implicit Minority Discount" in Delaware Appraisal Law, 156 University of Pennsylvania Law Review 1 (with Michael Wachter)

The Policy Foundations of Delaware Corporate Law, 106 Columbia Law Review 1749 (2006)

The Fair Value of Cornfields in Delaware Appraisal Law, 31 Journal of Corporation Law 101 (2006) (with Michael Wachter)

Twenty Years After Smith v. Van Gorkom*: An Essay On The Limits Of Civil Liability Of Corporate Directors And The Role Of Shareholder Inspection Rights*, 45 Washburn Law Review 301 (2006)

Ruby R. Vale and a Definition of Legal Scholarship, 31 Delaware Journal of Corporation Law 253 (2006)

Corporate Officers and the Business Judgment Rule: A Reply to Professor Johnson, 60 Business Lawyer 865 (2005) (with A. Gilchrist Sparks III)

Premiums in Stock for Stock Mergers and Some Consequences in the Law of Director Fiduciary Duties, 152 University of Pennsylvania Law Review 881 (2003)

The ABA Task Force on Professional Responsibility and the 2003 Changes to the Model Rules of Professional Conduct, 17 Georgetown Journal of Legal Ethics 35 (2003)

A Kinder, Gentler Critique of Van Gorkom *and its Less Celebrated Legacies*, 96 Northwestern Law Review 595 (2002)

Why I Do Not Teach Van Gorkom*,* 34 Georgia Law Review 477 (2000)

Corporate Democracy and Stockholder-Adopted By-Laws: Taking Back the Street?, 73 Tulane Law Review 409 (December 1998)

Calling Off the Lynch *Mob: The Corporate Director's Fiduciary Disclosure Duty*, 49 Vanderbilt Law Review 1087 (October 1996)

Common Law Duties of Non-Director Corporate Officers (with A. Gilchrist Sparks, III), 48 Business Lawyer 215 (1992)

"Appraisal Rights," chapter 36 of Drexler, Black and Sparks, DELAWARE CORPORATION LAW AND PRACTICE

EXPERT WITNESS, *AMICUS CURIAE* AND APPOINTMENTS (partial list)

In re Request of the Governor, 722 A.2d 307 (Del. 1998) (appointed by the Court *pro bono publico* to advocate on appointments clause of the State Constitution)

Goodrich v. E.F. Hutton Group, Inc., 681 A.2d 1039 (Del. 1996) (appointed by the Court to advocate on class action attorneys' fee award)

California Public Employees Retirement System v. Felzen, et al., 119 S.Ct. 720, 142 L.Ed.2d 766 (1999) (*amicus curiae* in support of petitioner on issue of appellate standing in stockholder derivative actions)

Onti, Inc. v. Integra Bank, 751 A.2d 904, 931-32 (Del. Ch. 1999) (expert witness on valuation of contingent claims including shareholder derivative claims)

In the Matter of Banc of America Capital Management, LLC, et al. and *In the Matter of Columbia Management Advisors, Inc.* (Securities and Exchange Commission, 2005-2009) (appointment as independent distribution consultant in connection with mutual fund settlements)

In the Matter of the Proposed Acquisition of Royal Indemnity Company, et al., in the Insurance Department of the State of Delaware (appointed as hearing officer in contested application for acquisition of control of Delaware property/casualty subsidiaries of Royal SunAlliance Insurance Group plc).

OTHER AFFILIATIONS

Music School of Delaware, director (2014 – 2020); Board Chair (2018 - 2020)
ACLU Delaware, Inc., director (1985-2015; President, 1996-2003); representative to the National Board of Directors (2004 –2009)
Wilmington Community Orchestra, violin
Ardensingers Orchestra, violin
Beth Israel Music Appreciation Society (BIMAS), Media, Pennsylvania

EXHIBIT B TO THE EXPERT REPORT OF LAWRENCE HAMERMESH

MATERIALS CONSIDERED

A. Discovery Materials Produced in the Bankruptcy Cases[1]

1. April 5, 2006 Compliance Report (PPLPC031000329746)
2. Nov. 2006 Compliance Report (PPLPC031000329745)
3. 1Q 2007 Quarterly Compliance Report (PPLP004399705)
4. Aug. 8, 2007 Compliance Report (PPLP004399954)
5. Oct. 31, 2007 Quarterly Compliance Report (PPLPC019000172297)
6. Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607)
7. 1Q 2008 Quarterly Compliance Report (PPLP004401169)
8. 2Q 2008 Quarterly Compliance Report (PPLP004401342)
9. 3Q 2008 Quarterly Compliance Report (PPLP004402032)
10. 4Q 2008 Quarterly Compliance Report (PPLP004402205)
11. 1Q 2009 Quarterly Compliance Report (PPLP004402651)
12. 2Q 2009 Quarterly Compliance Report (PPLPC012000236639)
13. 3Q 2009 Quarterly Compliance Report (PPLP004402982)
14. 4Q 2009 Quarterly Compliance Report (PPLP004403707)
15. 1Q 2010 Quarterly Compliance Report (PPLP004404102)
16. 2Q 2010 Quarterly Compliance Report (PPLP004404551)
17. 3Q 2010 Quarterly Compliance Report (PPLP004405460)
18. 4Q 2010 Quarterly Compliance Report (PPLP004405709)
19. 1Q 2011 Quarterly Compliance Report (PPLP004406032)
20. 2Q 2011 Quarterly Compliance Report (PPLP004406466)
21. 3Q 2011 Quarterly Compliance Report (PPLP004406790)
22. 4Q 2011 Quarterly Compliance Report (PPLP004407554)
23. 1Q 2012 Quarterly Compliance Report (PPLP004407950)
24. Jul. 19, 2012 Quarterly Compliance Report (PPLPUCC9002892662 and PPLP004408046)
25. 3Q 2012 Quarterly Compliance Report (PPLP004408439)
26. 4Q 2012 Quarterly Compliance Report (PPLP004409357)
27. 1Q 2013 Quarterly Compliance Report (PPLP004409694)
28. Jul. 25, 2013 Quarterly Compliance Report (PPLP004409783)
29. 3Q 2013 Quarterly Compliance Report (PPLP004410506)
30. 4Q 2013 Quarterly Compliance Report (PPLP004410797)
31. 1Q 2014 Quarterly Compliance Report (PPLP004411166)
32. 2Q 2014 Quarterly Compliance Report (PPLP004411277)
33. 4Q 2014 Quarterly Compliance Report (PPLP004411811)
34. 1Q 2015 Quarterly Compliance Report (PPLP004412071)
35. 2Q 2015 Quarterly Compliance Report (PPLP004412152)
36. 3Q 2015 Quarterly Compliance Report (PPLP004412546)

[1] Each document is identified by its first bates numbered page.

37. 4Q 2015 Quarterly Compliance Report (PPLPC063000018836 and PPLP004412818)
38. Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544)
39. 3Q 2016 Quarterly Compliance Report (PPLPUCC9002790025)
40. Mar. 2017 Quarterly Compliance Report (PPLP004413913)
41. Jun. 2017 Quarterly Compliance Report (PPLP004414244)
42. Aug. 2017 Quarterly Compliance Report (PPLPC021000899767)
43. 3Q 2017 Quarterly Compliance Report (PPLPC022001020792)
44. Dec. 2017 Quarterly Compliance Report (PPLPC021000920798)
45. Mar. 2018 Quarterly Compliance Report (PPLP004414931)
46. Aug. 10, 2018 Quarterly Compliance Report (PPLP004415061)
47. July 13, 2005 Board Report (PPLPC026000024332)
48. Jan. 31, 2005 Report to the Board (PPLPC013000125609)
49. Apr. 15, 2005 Report to the Board (PPLPC022000070889)
50. 1Q 2006 Board Report (PPLPC036000067805)
51. 2Q 2006 Board Report (PPLPC026000027526)
52. 3Q 2006 Board Report (PPLPC036000073187)
53. 4Q 2006 Board Report (PPLP004367696)
54. 1Q 2007 Board Report (PPLP004367733)
55. 2Q 2007 Board Report (PPLP004366645)
56. 3Q 2007 Board Report (PPLPC012000157402)
57. 4Q 2007 Board Report (PPLP004367604)
58. 1Q 2008 Board Report (PPLP004367134)
59. 2Q 2008 Board Report (PPLP004367297)
60. 3Q 2008 Board Report (PPLP004367232)
61. 4Q 2008 Board Report (PPLP004367067)
62. 1Q 2009 Board Report (PPLP004367262)
63. 2Q 2009 Board Report (PPLPC012000233231)
64. 3Q 2009 Board Report (PPLP004367330)
65. 4Q 2009 Board Report (PPLP004367162)
66. 1Q 2010 Board Report (PPLP004317547)
67. 2Q 2010 Board Report (PPLP004367018)
68. 3Q 2010 Board Report (PPLP004366991)
69. 4Q 2010 Board Report (PPLP004366955)
70. 1Q 2011 Board Report (PPLPC012000322426)
71. 2Q 2011 Board Report (PPLP004366913)
72. 3Q 2011 Board Report (PPLP004366871)
73. 4Q 2011 Board Report (PPLPC012000362869)
74. 1Q 2012 Board Report (PPLPC012000374791)
75. 2Q 2012 Board Report (PPLPC012000387069)
76. 3Q 2012 Board Report (PPLP004366816)
77. 4Q 2012 Board Report (PPLP004366760)
78. 1Q 2013 Board Report (PPLP004367540)
79. 2Q 2013 Board Report (PPLPC012000433388)
80. 3Q 2013 Board Report (PPLPC002000186911)
81. 4Q 2013 Board Report (PPLPC002000181035)

82. 1/15/07 Board Agenda (PPLP004400562)
83. 2/8/07 Board Agenda (PPLP004400572)
84. 3/2/07 Board Agenda (PPLP004400597)
85. 4/24/07 Board Agenda (PPLP004399675)
86. 5/11/07 Board Agenda (PPLP004399813)
87. 6/29/07 Board Agenda (PPLP004399909)
88. 8/6/07 Board Agenda (PPLP004399952)
89. 9/28/07 Board Agenda (PPLP004399991)
90. 11/1/07 Board Agenda (PPLP004400527)
91. 11/15/07 Board Agenda (PPLP004400551)
92. 1/11/08 Board Agenda (PPLP004400663)
93. 2/8/08 Board Agenda (PPLPC030000417143)
94. 2/14/08 Board Agenda (PPLP004400864)
95. 3/10/08 Board Agenda (PPLP004401017)
96. 4/18/08 Board Agenda (PPLPC012000179049)
97. 5/16/08 Board Agenda (PPLP004401143)
98. 6/27/08 Board Agenda (PPLP004401328)
99. 8/8/08 Board Agenda (PPLP004401340)
100. 9/26/08 Board Agenda (PPLP004401475)
101. 11/4/08 Board Agenda (PPLP004402136)
102. 1/15/09 Board Agenda (PPLP004402162)
103. 2/5/09 Board Agenda (PPLP004402229)
104. 3/5/09 Board Agenda (PPLP004402377)
105. 4/14/09 Board Agenda (PPLP004402432)
106. 5/8/09 Board Agenda (PPLP004402584)
107. 6/26/09 Board Agenda (PPLP004402697)
108. 7/23/09 Board Agenda (PPLP004402709)
109. 9/23/09 Board Agenda (PPLP004402802)
110. 10/19/09 Board Agenda (PPLP004402881)
111. 11/3/09 Board Agenda (PPLPUCC9002964468)
112. 11/20/09 Board Agenda (PPLP004403588)
113. 1/21/10 Board Agenda (PPLPC044000023970)
114. 2/4/10 Board Agenda (PPLPC053000038938)
115. 3/11/10 Board Agenda (PPLP004403811)
116. 4/1/10 Board Agenda (PPLPC012000265396)
117. 5/6/10 Board Agenda (PPLP004404073)
118. 6/25/10 Board Agenda (PPLP004404454)
119. 7/22/10 Board Agenda (PPLP004404478)
120. 8/26/10 Board Agenda (PPLPC053000043567)
121. 9/23/10 Board Agenda (PWG004349878)
122. 10/21/10 Board Agenda (PPLP004404784)
123. 11/03/10 Board Agenda (PPLP004405427)
124. 11/19/10 Board Agenda (PPLP004405511)
125. 1/20/11 Board Agenda (PPLP004405607)
126. 2/3/11 Board Agenda (PPLPC018000480936)
127. 3/1/11 Board Agenda (PPLP004405789)

128. 4/14/11 Board Agenda (PPLP004405858)
129. 5/20/11 Board Agenda (PPLP004405990)
130. 6/24/11 Board Agenda (PPLP004406301)
131. 7/21/11 Board Agenda (PPLPC054000086946)
132. 8/11/11 Board Agenda (PWG004351884)
133. 9/1/11 Board Agenda (PPLP004406668)
134. 10/13/11 Board Agenda (PWG004351934)
135. 11/02/11 Board Agenda (PPLPC037000102197)
136. 11/17/11 Board Agenda (PPLP004406952)
137. 1/19/12 Board Agenda (PPLP004407542)
138. 2/15/12 Board Agenda (PPLP004407735)
139. 4/26/12 Board Agenda (PPLP004407765)
140. 6/22/12 Board Agenda (PPLP004407956)
141. 7/19/12 Board Agenda (PPLPC051000150959)
142. 8/16/12 Board Agenda (PPLP004408065)
143. 9/13/12 Board Agenda (PPLP004408301)
144. 10/4/12 Board Agenda (PWG004353617)
145. 11/2/12 Board Agenda (PPLP004409073)
146. 11/16/12 Board Agenda (PPLP004409271)
147. 12/6/12 Board Agenda (PPLPC037000119373)
148. 1/15/13 Board Agenda (PPLPC049000070397)
149. 2/13/13 Board Agenda (PPLP004409377)
150. 3/21/13 Board Agenda (PPLPC044000041897)
151. 4/10/13 Board Agenda (PPLP004409601)
152. 5/2/13 Board Agenda (PPLP004409708)
153. 6/7/13 Board Agenda (PPLP004409774)
154. 7/25/13 Board Agenda (PPLP004409781)
155. 8/15/13 Board Agenda (PPLP004409890)
156. 9/12/13 Board Agenda (PPLPC046000054971)
157. 10/3/13 Board Agenda (PPLPC039000984972)
158. 11/1/13 Board Agenda (PPLP004410504)
159. 11/15/13 Board Agenda (PPLP004410516)
160. 12/16/13 Board Agenda (PWG004355938)
161. 1/16/14 Board Agenda (PPLP004410692)
162. 2/26/14 Board Agenda (PPLP004410816)
163. 4/21/14 Board Agenda (PPLP004410817)
164. 5/15/14 Board Agenda (PPLP004411049)
165. 6/2/14 Board Agenda (PPLPC039001044053)
166. 8/14/14 Board Agenda (PPLP004411233)
167. 10/1/14 Board Agenda (PPLP004411288)
168. 11/4/14 Board Agenda (PPLPC016000262496)
169. 1/15/15 Board Agenda (PPLP004411807)
170. 3/11/15 Board Agenda (PPLP004411894)
171. 4/21/15 Board Agenda (PPLPC011000025791)
172. 6/11/15 Board Agenda (PPLPC037000209682)
173. 8/19/15 Board Agenda (PPLP004412123)

174. 10/6/15 Board Agenda (PPLP004412226)
175. 12/17/15 Board Agenda (PPLP004412555)
176. 1/15/16 Board Agenda (PPLP004412586)
177. 3/9/16 Board Agenda (PPLPC053000111461)
178. 4/15/16 Board Agenda (PPLPC046000071895)
179. 6/9/16 Board Agenda (PPLP004413180)
180. 8/23/16 Board Agenda (PPLP004413348)
181. 10/27/16 Board Agenda (PPLP004413452)
182. 12/8/16 Board Agenda (PPLP004413791)
183. 2/1/17 Board Agenda (PPLP004413815)
184. 3/8/17 Board Agenda (PPLP004413871)
185. 4/5/17 Board Agenda (PPLPC051000314340)
186. 6/15/17 Board Agenda (PPLPC018001437163)
187. 8/23/17 Board Agenda (PPLP004414342)
188. 10/19/17 Board Agenda (PPLPUCC9002310385)
189. 11/30/17 Board Agenda (PPLPUCC9002310410)
190. 1/30/18 Board Agenda (PPLP004414567)
191. 3/8/18 Board Agenda (PPLP004414881)
192. 3/12/97 Memorandum from John Stewart (PDD1701785443)
193. 10/20/00 Performance Planning and Review (PPLP004411692)
194. 1/9/01 Email from Robert Kaiko with Attachment (PPLPC013000062006)
195. 2/1/01 Email from Richard Sackler (PDD8801133516)
196. 2/8/01 Email from Richard Sackler (PPLPC045000004037)
197. 7/18/01 Purdue Dear HCP Letter (PDD1715240425)
198. 10/15/02 ADD SOP (PDD1503450011)
199. 11/1/02 ADD SOP 1.7.1 (PPLP003430434)
200. 1/17/03 Letter from FDA (PPLPC030000174935)
201. 3/12/03 SOM SOP (PPLPC035000019501)
202. 9/22/03 Email from Ted Hester with Attachment (BATES No. 9101439815)
203. 10/6/03 ADD SOP 1.7.1 (PDD1503493410)
204. 6/11/04 Compliance Program Presentation (PPLPC015000020647)
205. 8/16/04 Email from Michael Friedman (PPLPUCC002500463)
206. 11/18/04 Email from Michael Friedman (PPLPUCC002299712
207. 12/15/04 Settlement Agreement and Release, *State of West Virginia v. Purdue Pharma, L.P.*, No. 01-CV-137 (W. Va. Cir. Ct. McDowell Cty.) (VF 00932234)
208. 1/31/05 Report to the Board (PPLPUCC9007198580)
209. 2/17/05 Email from Michael Friedman (PPLPUCC003351779)
210. 8/22/05 Sales Training and Development re: Reporting of Adverse Events (PDD1503520499)
211. 9/20/05 Email from Bert Weinstein to Board (PPLPC036000062443)
212. 11/1/05 Budget Presentation (PPLPC018000070210)
213. 10/11/06 Examples of Purdue's Anti-Abuse and Diversion Efforts (PPLPUCC9002443564)
214. 12/4/06 Corporate Compliance Council Meeting (PPLPC012000126216)
215. 12/18/06 Compliance Presentation to OIG (PPLP004430145)
216. 6/15/07 ADD SOP 1.7.1 (PPLP003429997)

217. 6/20/07 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000033097)
218. 10/28/07 Email from Edward Mahony (PPLPC012000159168)
219. 11/28/07 Compliance Officer Certification (PPLP004432089)
220. 1/24/08 Email to Board with Executive Committee Minutes (PPLPC041000006381)
221. 1/30/08 Email from Richard Sackler (PPLPC012000168321)
222. 2/13/08 Email from John Stewart (PPLPC013000244843)
223. 2/14/08 Email from Russell Gasdia (PPLPC012000170948)
224. 2/20/08 Email from David Rosen (PPLPC004000150467)
225. 2/24/08 Email from Ake Wikstrom (PPLPUCC000258570)
226. 2/26/08 Email from Richard Sackler (PPLPC012000172674)
227. 3/8/08 Email to Board with Executive Committee Minutes (PPLPC044000015917)
228. 3/8/08 Email from Russell Gasdia (PPLPC012000174127)
229. 3/9/08 Email from Russell Gasdia (PPLPC012000174202)
230. 3/10/08 Email from John Stewart (PPLPC012000174476)
231. 3/16/08 Email from Edward Mahony (PPLPC012000175155)
232. 3/19/08 Executive Committee Meeting Notes and Actions (PPLPC044000015919)
233. 4/22/08 Email from Richard Sackler (PPLPC012000179497)
234. 4/23/08 Email from Russell Gasdia (PPLPC012000179679)
235. 5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000041921)
236. 5/15/08 Email from Jonathan Sackler (PPLPC042000013801)
237. 5/15/08 Letter from Virginia AG (PPLPC049000021023)
238. 7/30/08 Sales Force SOP (PPLP003342665)
239. 9/12/08 Executive Committee Notes (PPLPC053000030108).
240. 11/19/08 Memo from Law Department Summarizing Investigation (PWA001272123)
241. 2/11/09 Compliance Memo (PPLPC051000068931)
242. 3/23/09 OMS SOP (PPLPUCC9011108993)
243. 5/6/09 OIG Letter to Purdue (PPLPC044000019807)
244. 5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PWG004407107)
245. 5/18/09 Purdue Letter to Virginia AG (PPLPC051000075710)
246. 5/20/09 Email from Richard Sackler (PPLPC061000042437)
247. 5/20/09 Executive Committee Meeting Notes (PPLPC041000008788)
248. 6/1/09 Email from Jonathan Sackler (PPLPC012000225228)
249. 6/16/09 Email from David Rosen (PPLPC012000225228)
250. 9/16/09 Executive Committee Meeting Notes and Actions (PPLPC049000029886)
251. 7/20/09 Email from Richard Sackler (PPLPC012000232015)
252. 8/12/09 Email from Richard Sackler (PPLPC012000234970)
253. 8/17/09 Presentation to Board (PPLPC012000235543)
254. 9/25/09 Email from Mortimer Sackler (PURDUE-COR-00025380)

255. 9/25/09 Second Annual Report under CIA (PPLPC063000000289)
256. 9/30/09 Email to Board with Executive Committee Minutes (PPLPC049000029885)
257. 10/8/09 Email from Richard Sackler (PDD9316309168)
258. 10/8/09 Email from Richard Sackler (PPLPC012000241515)
259. 10/28/09 Sales and Marketing Compliance Committee Agenda (PPLP004436174)
260. 1/18/10 Scorecard Summary (PPLPC057000007180)
261. 1/21/10 Amendment to Shareholder Agreement (PPLP004415716)
262. 1/25/10 Email from Mortimer Sackler (MSF00024901)
263. 2/18/10 Promotion Monitoring Program Working Practice Document (PPLP004431206)
264. 2/24/10 Board Proposal (PURDUE-COR-00028015)
265. 3/15/10 Email from Mike Innaurato (PPLPC012000262889)
266. 4/1/10 OIG Letter to Purdue (PPLP004250164)
267. 5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000064681)
268. 5/13/10 Letter from Virginia AG (PTN000030085)
269. 7/1/10 Email from Richard Sackler (PPLPC012000277480)
270. 7/21/10 Presentation to Corporate Compliance Council entitled “The Order Monitoring System” (PPLPC041000011499)
271. 7/22/10 Butrans Commercial Strategy Plan Board Presentation (PPLPC018000404193)
272. 7/22/10 Questions Arising During Purdue Pharma Shareholders and Board Meeting (PPLPC012000283163)
273. 7/22/10 Attachment to Questions Arising During Purdue Pharma Shareholders and Board Meeting (PPLPC012000283175)
274. 8/15/10 Email from John Stewart (PPLPC012000283047)
275. 11/10/10 Executive Committee Meeting Notes and Actions (PPLPC012000299852)
276. 11/24/10 Email to Board with Executive Committee Minutes (PPLPC012000299851)
277. 1/21/11 Board Compensation Committee deck (PPLPUCC9003754547 and PPLPC051000109841)
278. 1/28/11 OIG Letter to Purdue (PPLPC051000129176)
279. 1/30/11 Email from Richard Sackler (PPLPC021000352205)
280. 1/31/11 Email from Richard Sackler (PPLPC012000308393)
281. 2/15/11 Email from Jonathan Sackler (PPLPUCC9003800123)
282. 3/7/11 Letter from Ohio AG (PPLPC051000114667)
283. 3/28/11 Letter from Joe Biden (PPLPC019000512544)
284. 4/12/11 Email from Jack Crowley to Burt Rosen, *et al.* (PPLPC053000051168)
285. 4/13/11 Email from Kimberly Gadski (PPLPC012000320101)
286. 4/14/11 Email from Jack Crowley (PPLPC053000051213)
287. 4/20/11 Email from Robin Abrams (PWA001487465)
288. 5/3/11 Email from John Stewart (PPLPC042000023301 and PPLPUCC9000363533)
289. 5/18/11 Beneficiaries Presentation (PPLPC037000098187)

290. 5/25/11 Email from Jonathan Sackler (PPLPC012000326096)
291. 5/25/11 Email to Board (PPLPC012000326017)
292. 5/25/11 Email from Russell Gasdia (PPLPC012000326193)
293. 6/16/11 Email from Bert Weinstein (PPLPC012000329722)
294. 6/16/11 Email from Mabel Herson (PPLPC012000329609)
295. 6/16/11 Email from Richard Sackler (PPLPC012000329706)
296. 6/28/11 Board Meeting Notes (PPLPC012000331345)
297. 7/13/11 Email from Rebecca Glynn (PPLPUCC9002386750)
298. 7/20/11 Emails with Richard Sackler (PPLPC001000091102)
299. 8/3/11 Email to Board with Executive Committee Minutes with Attachment (PPLPC012000337158)
300. 9/23/11 Fourth Annual Report under CIA (PPLPC032000397973)
301. 10/3/11 Email from J. Crowley to DOJ with Attachment (PPLP004437148)
302. 10/3/11 Email from Edward Mahony (PPLPC012000345892)
303. 10/7/11 Email from Jack Crowley to DEA (PPLP004437144)
304. 10/25/11 Exec. Comm. Notes Sent to Board (PURDUE-COR-00032185)
305. 10/25/11 Attachment to Exec. Comm. Notes Sent to Board (PURDUE-COR-00032186)
306. 11/3/11 Beneficiaries Presentation (PPLPC034000597805)
307. 12/9/11 Presentation entitled “Epidemiology studies of Reformulated OxyContin's effect on opioid abuse” (PPLPC019000618954)
308. 1/9/12 Email from Jonathan Sackler (PPLPC012000358983)
309. 1/18/12 Board Compensation Committee Presentation (PPLPC042000025057)
310. 1/18/12 President’s Review of Significant Accomplishments and Disappointments in 2011 (PPLPC042000025039)
311. 2/7/12 Email from Richard Sackler (PPLPC012000368430)
312. 2/8/12 Email from Bert Weinstein (PPLPC026000095655)
313. 2/15/12 Law Department Memo (PWA001433067)
314. 2/27/12 SOP for Analgesic Sales Force (PPLPC014000164042)
315. 3/5/12 Email from Richard Sackler (PPLPC042000025391)
316. 3/8/12 Email from Russell Gasdia (PPLPC012000368569)
317. 3/8/12 OIG Letter to Purdue (PPLP004428603)
318. 3/12/12 Email from David Rosen (PPLPC012000368823)
319. 3/28/12 Email from David Rosen (PPLPC012000371301)
320. 4/20/12 Product Promotional Guidelines (PPLP003517436)
321. 4/27/12 Email from Windell Fisher (PPLPC020000573909)
322. 6/12/12 Email from William Mallin with Attachment (PPLPC057000011188)
323. 6/12/12 Board Presentation (PPLPC057000011194)
324. 7/26/12 Email to Board with Executive Committee Minutes with Attachment (PPLPC057000011447)
325. 9/9/12 Email from Edward Mahony (PPLPC012000390509)
326. 11/3/12 Beneficiaries’ Meeting Book (PPLP004409088)
327. 1/21/13 Presentation to Compensation Committee (PPLPC045000016839)
328. 1/24/13 OIG Letter to Purdue (PPLP004427723)
329. 2/27/13 Letter from Connecticut Governor (PPLPC020000776814)
330. 4/10/13 Email from Russell Gasdia (PPLPC012000417566)

331. 4/18/13 Email from Jonathan Sackler (RSF00036311)
332. 5/19/13 email from David Rosen (PPLPC012000424137)
333. 6/5/13 Email to the Board and Others (PPLPC057000014144)
334. 6/6/13 Managed Care Board Slides (PPLPC063000016119)
335. 7/18/13 Memorandum from McKinsey (MDSF00986955)
336. 8/2/13 Response to LA Times (PPLPC031001086873)
337. 8/5/13 Email from Arnab Ghatak (MCK-MAAG-0112708)
338. 8/15/13 Email from Mortimer Sackler (PPLPUCC9002451449)
339. 8/23/13 Email from Richard Sackler (PPLPUCC9002962793)
340. 8/26/13 Email from Jeanette Park (MCK-MAAG-0112331)
341. 8/27/13 Nevada State Board of Medical Examiners Letter (PPLPC049000076533)
342. 8/30/13 Memo from Law Department Summarizing Investigation (PWA001272114)
343. 9/3/13 Nevada State Board of Pharmacy Letter (PPLPC049000079271)
344. 9/10/13 FDA Response to PROP Petition (PPLPC019000835061)
345. 9/11/13 California Medical Board Letter (PPLPC049000079268)
346. 9/12/13 Presentation to Board (PPLPC063000002005)
347. 9/12/13 California Dental Board Letter (PPLPC051000189775)
348. 9/13/13 Letter to Eastern District of Pennsylvania AUSA (PPLPC049000079240)
349. 9/13/13 McKinsey Presentation (PPLPUCC9008739108)
350. 9/17/13 Panel Transcript (PPLPC018000884102)
351. 9/25/13 California Board of Registered Nursing Letter (PPLP004437542)
352. 9/25/13 California Medical Board Letter (PPLPC051000189745)
353. 9/25/13 California Osteopathic Medical Board Letter (PPLPC051000189739)
354. 9/26/13 California Board of Podiatric Medicine Letter (PPLPUCC9011507904)
355. 9/26/13 California Physician Assistant Board Letter (PPLPUCC9011507902)
356. 9/26/13 Nevada State Board of Osteopathic Medicine Letter (PPLPUCC9011507906)
357. 10/10/13 Purdue Letter to Tennessee AG (PPLPC049000079234)
358. 10/15/13 Tennessee Office of Attorney General Letter (PPLP004438085)
359. 10/16/13 Presentation entitled “Update on Findings Regarding Reformulated OxyContin” (PPLPC020000725746)
360. 11/1/13 Email from Gary Stiles re “Board Notes & Actions” (PPLPC012000449535)
361. 11/8/13 New Jersey Office of Attorney General (PPLP004437814)
362. 11/16/13 Beneficiaries’ Meeting Book (PPLPC051000193984)
363. 11/18/13 Email from John Stewart (PPLPC012000452389)
364. 12/16/13 Letter from AGs to FDA (PPLPC046000057423)
365. 12/17/13 Presentation to E2E Executive Oversight Team (PPLPC014000232245)
366. 1/3/14 Email from Jonathan Sackler (PPLPC020000748356)
367. 1/7/14 Letter to Senators (PPLPC049000103061)
368. 2/12/14 Illinois Department of Financial and Professional Regulation Letter (PPLP004437654)
369. 2/19/14 Virginia Department of Health Professions Letter (PPLP004438105)
370. 2/25/14 Wisconsin Department of Safety & Professional Services Letter (PPLP004438118)

371. 2/26/14 Wyoming Board of Medicine Letter (PPLP004438157)
372. 2/27/14 Georgia Composite Medical Board Letter (PPLP004437620)
373. 2/27/14 West Virginia Board of Medicine Letter (PPLP004438134)
374. 2/27/14 West Virginia Board of Osteopathic Medicine Letter (PPLP004438138)
375. 2/28/14 Arizona Board of Osteopathic Examiners in Medicine and Surgery Letter (PPLP004437482)
376. 2/28/14 Pennsylvania Department of State, Bureau of Professional/Occupational Affairs (PPLP004437994)
377. 3/4/14 Kansas State Board of Healing Hearts Letter (PPLP004437673)
378. 3/7/14 North Dakota State Board of Medical Examiners (PPLP004437795)
379. 3/11/14 Alabama State Board of Medical Examiners Letter (PPLP004437472)
380. 3/11/14 Rhode Island Board of Medical Licensure & Discipline Letter (PPLP004438019)
381. 3/12/14 Letter to Senators (PPLPC049000103152)
382. 3/13/14 Email from John Goldie (MCK-MAAG-0119088)
383. 4/28/14 Wisconsin Department of Safety & Professional Services Letter (PPLP004438113)
384. 5/5/14 Email from Raymond Sackler with Attachment (PWG000412141)
385. 5/20/14 Oregon Medical Board Letter (PPLPUCC9011455002)
386. 6/10/14 Email from Richard Sackler (PAZ000099416)
387. 7/1/14 Flash Report (PPLPC016000244173)
388. 8/5/14 Flash Report (PPLPC016000250753)
389. 8/13/14 JPMorgan Presentation (PPLP-NRF-000016462)
390. 9/5/14 Flash Report (PPLPC016000254916)
391. 10/7/14 Email from David Sackler to Jonathan Sackler (PPLPUCC002907060)
392. 10/15/14 Flash Report (PPLPC016000259607)
393. 11/15/14 Email from Jonathan Sackler (RSF_OLK00040227 and PPLPC045000017193)
394. 6/11/15 Draft MNP Decision Document (PPLPUCC9002721550)
395. 6/20/15 Email from Theresa Sackler (PPLPUCC9004448656)
396. 6/26/15 Email from Stephen Ives (RSF_OLK00021303)
397. 7/13/15 Email from Stephen Ives with Attachment (RSF00471979)
398. 8/11/15 Nevada State Board of Medical Examiners Letter (PPLPUCC9011512808)
399. 8/13/15 Email from David Sackler (RSF_OLK00021534)
400. 12/10/15 Executive Committee Presentation (PPLPC011000073230)
401. 12/18/15 settlement between Purdue and Kentucky (PPLPUCC000701839)
402. 2/5/16 ADD Program Working Practice Document (POK003723668)
403. 3/30/16 Letter from Moody's (PPLPUCC003938943)
404. 4/7/16 Letter from Standard & Poor's (PPLPUCC000360920)
405. 5/17/16 Nevada State Board of Medical Examiners Letter (PPLPUCC9011562267)
406. 6/10/16 Email to Board (PPLPC011000106533)
407. 10/7/16 Auditor's First Report on Purdue's ADD Program (PPLP004473667)
408. 12/7/16 MNP Consulting Limited Board Agenda (PPLPUCC9002689883)
409. 5/5/17 Email from Craig Landau (PWG004670879)

410. 5/5/17 Memo from Mark Timney (PPLPC051000317758)
411. 5/15/17 Memo from Raman Singh (PPLPC051000317750)
412. 10/20/17 Auditor's Second Report on Purdue's ADD Program (PPLP004473709)
413. 11/21/17 Email from Jonathan Sackler (PPLPC016000321333)
414. 1/25/18 ADD Program Working Practices Document (PPLPC023000971903)
415. 10/19/18 Auditor's Third Report on Purdue's ADD Program (PPLP004473738)
416. Oct. 2007 Budget Presentation (PPLP004400043)
417. Oct. 2007 Healthcare Law Compliance Policies (PCA000008811)
418. Apr. 2008 Draft Memorandum (PDD9316300630)
419. Nov. 2010 Budget Presentation Notes and Actions (PPLPC012000245368)
420. Nov. 2010 Sales & Marketing Presentation to Board (PPLP004404901)
421. Oct. 2011 Full Budget Presentation (PPLPUCC003392177)
422. Oct. 2011 Guidelines on Product Promotion Comparative Claims Workshop (PPLP003439475)
423. Nov. 2011 Budget Presentation (PPLP004406990)
424. Nov. 2011 Summary of Findings of Post-Marketing Epidemiology Study Program (PPLPC021000435532)
425. May 2012 Presentation (PPLPC012000378037)
426. Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110)
427. Jan. 2013 Sales Force SOP (PPLP003430093)
428. Nov. 2013 Budget Presentation (PPLP004409973)
429. Nov. 2014 Budget Presentation to Board (PPLP004411368)
430. Aug. 2015 Budget Presentation (PPLPC051000265076)
431. Sept. 2015 ADD SOP 1.7.1 (PPLP004035073)
432. Dec. 2016 Budget Presentation (PPLP004413542)
433. Jan. 2016 Sales Force SOP Manual (PPLP003578668)
434. Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429)
435. Oct. 2017 Board Presentation (PPLPC054000140481)
436. 1995 OxyContin FDA-Approved Label (PPLPC044000064536)
437. 1996 PFC Newsletter (PDD1701059996)
438. 2001 OxyContin FDA-Approved Label (PDD1501070063)
439. 2003 Partners Against Pain, Pain Management Kit (PDD1501615472)
440. 2003 Purdue's Internal Investigations Summary (9101439816)
441. 2005 Corporate Compliance Charter (PKY183307471)
442. 2007 Connecticut Complaint (PPLPC051000040740)
443. 2007 Decision Documents (PPLP004416560)
444. 2007 New York Medicaid Settlement (PPLPC051000047401)
445. 2007 Utah Medicaid Settlement (PPLPC030000403177)
446. 2008 Decision Documents (PPLP004416667)
447. 2008 Training Materials (PPLP003550586)
448. 2009 Decision Documents (PPLP004416787)
449. 2009 Guidelines on Product Promotion (PPLP004433671)
450. 2010 Decision Documents (PPLP004417012)
451. 2010 OxyContin FDA-Approved Label (PDD8901035967)
452. 2011 Decision Documents (PPLP004417130)
453. 2012 Budget Presentation to the Board (PPLPUCC9011086649)

454. 2012 Decision Documents (PPLP004417222)
455. 2013 Decision Documents (PPLP004417308)
456. 2013 OxyContin FDA-Approved Label (PPLPC003000060503)
457. 2014 Decision Documents (PPLP004417396)
458. 2014 RADARS System Report (PPLP004466970)
459. 2015 Assurance of Discontinuance (PPLP004035441)
460. 2015 Decision Documents (PPLP004417483)
461. 2016 Decision Documents (PPLP004417586)
462. 2017 Decision Documents (PPLP004417653)
463. 2017 Memo to Ake Wikstrom (PPLPC051000317768)
464. 2018 Decision Documents, through June 28, 2018 (PPLP004417729)
465. A Training Guide for Healthcare Providers (PTN000000596)
466. Amended and Restated Limited Partnership of PPLP Agreement dated as of January 2, 1997 (PDD9316726090)
467. Amendments to By-Laws of April 18, 2008 (PPLP004415363)
468. Certificate of Amendment of Certificate of Incorporation of PPI dated July 30, 2012 (PPLP004415886)
469. Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion (PPLPC042000024694)
470. Clinical Issues in Opioid Prescribing (PPLP003517021)
471. Daniel Brookoff, *Abuse Potential of Various Opioid Medications*, 8 J. GEN. INTERN. MED. 688, 690 (1993) (PPLPC013000157356)
472. Description of Reporting Suspicious Prescribers (PPLPUCC9002443722)
473. Governance Process (PPLPUCC9003577789)
474. Harriet de Wit, et al., *Rate of Increase of Plasma Drug Level Influences Subjective Response in Humans*, PSYCHOPHARMACOLOGY 107:352, 358 (1992) (PKY181753181)
475. Internal Inquiries: Procedures (PPLPC019000213919)
476. IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 1 (PPLPC057000008159)
477. IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2 (PPLP004433812)
478. IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 2 (PPLP004433931)
479. IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3 (PPLP004434741)
480. IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 3 (PPLP004434456)
481. IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4 (PPLPC021000573227)
482. IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4 (PPLP004432560)
483. IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 5 (PPLP004434983 and PPLPC019000720508)
484. MA-DSP-SOP-000001 (PPLPUCC002500202)

485. MA-DSP-SOP-000002-Postmarketing Adverse Event Capture and Reporting (PPLP004392219)
486. McKinsey Statement of Services (PPLPC051000178707)
487. Minutes of the PPI Board (PPLP004415256)
488. Notes of October 2014 PPI Board meeting (PPLPBN-00002063)
489. Notes of October 2016 PPI Board meeting (PPLPBN-00002815)
490. OMS Tracker, Excerpted (PPLP004474496)
491. PPI Board of Directors List (PPLPUCC500140094)
492. PPI By-Laws (PUT000010519)
493. PPLP's ADD Program Background (PPLPC031001431032)
494. Providing Relief (PPLP003516982)
495. Purdue Healthcare Law Compliance Policies (PCA000008931)
496. Purdue SOP Num. GC-SOP-0001.04, Retention of HealthCare Professionals as Consultants, Advisors and Speakers (PPLP003364388)
497. Purdue SOP Num. GC-SOP-0002, Material Review Process (POK003707782)
498. Purdue SOP Num. REG-SOP-0060, Material Approval Process (PWA000000769)
499. Restated Certificate of Incorporation of PPI as of March 4, 2003, (PKY180173691 and PDD1506030024)
500. RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel (PPLPC039000340008)
501. RM-SOP-000001.1-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel (PPLPC030000250901)
502. Third Amended and Restated Limited Partnership of PPLP dated as of March 7, 2018 (PUT000010556)
503. William H. Oldendorf, *Some Relationships Between Addiction and Drug Delivery to the Brain*, NIDA RESEARCH MONOGRAPH 120:13 (1992) (PKY181870332)

B. <u>Documents Filed in the Bankruptcy Cases</u>

504. September 16, 2019 Debtors' Informational Brief (ECF No. 17)
505. November 6, 2019 Declaration of Patrick Fitzgerald in Support of Application of Debtors for Authority to Retain and Employ Skadden, Arps, Slate, Meagher & Flom LLP as Special Counsel to the Debtors *Nunc Pro Tunc* to the Petition Date (ECF No. 438-2)
506. December 16, 2019 AlixPartners Cash Transfers of Value Analysis (ECF No. 654-1)
507. September 30, 2020 Official Committee of Unsecured Creditors' Motion to Compel Production of Purportedly Privileged Documents, or for *In Camera* Review, Based on Good Cause, Crime Fraud, and at Issue Exceptions to Claims of Privilege (ECF No. 1753)
508. September 30, 2020 Declaration of Mitchell Hurley (ECF No. 1754), and exhibits thereto
509. October 15, 2020 Debtors' Omnibus Objection to the Official Committee's Motions to Compel Productions of the Debtors' Privileged Document and Cross-Motion for a Protective Order (ECF No. 1808)

510. October 15, 2020 Declaration of Benjamin S. Kaminetzky in Support of Debtors' Omnibus Objection to the Official Committee's Motions to Compel Productions of the Debtors' Privileged Document and Cross-Motion for a Protective Order (ECF No. 1809)
511. October 15, 2020 The Raymond Sackler Family's Opposition to the Official Committee of Unsecured Creditors' Exceptions Motion (ECF No. 1811)
512. October 15, 2020 Declaration of Mara Leventhal (ECF No. 1812), and exhibits thereto
513. November 18, 2020 The Ad Hoc Group of Non-Consenting States' Statement in Support of the Official Committee of Unsecured Creditors' Motions to Compel Production of Purportedly Privileged Documents or for *In Camera Review*, and exhibits thereto (ECF No. 2012)
514. November 19, 2020 Official Committee of Unsecured Creditors' Reply in Support of Its Motion to Compel Production of Purportedly Privileged Documents, or for *In Camera* Review, Based on Good Cause, Crime Fraud, and at Issue Exceptions to Claims of Privilege (ECF No. 2164)
515. November 19, 2020 Declaration of Arik Preis (ECF No. 2015), and exhibits thereto
516. December 9, 2020 The Raymond Sackler Family's Surreply in Further Support of its Opposition to the Official Committee of Unsecured Creditors' Exceptions Motion (ECF No. 2093)
517. December 9, 2020 Declaration of Mara Leventhal (ECF No. 2094), and exhibits thereto
518. March 15, 2021 Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and its Affiliated Debtors (ECF No. 2487)
519. March 15, 2021 Disclosure Statement for Chapter 11 Plan for Purdue Pharma L.P. and its Affiliated Debtors (ECF No. 2488)

C. <u>Documents Filed in Other Actions</u>

520. Complaint, *Commonwealth of Massachusetts v. Purdue Pharma, L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty. June 13, 2018)
521. Complaint, *People of California v. Purdue Pharma L.P., et al.*, Case No. 19STC19045 (Cal. Super. Ct. Los Angeles Cnty. June 3, 2019)
522. Consent Judgment, *In re Purdue Pharma L.P.*, No. 07-C-00740 (Ky. Cir. Ct., Franklin Cty. May 8, 2007)
523. First Amended Complaint, *Commonwealth of Massachusetts v. Purdue Pharma, L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty. Jan. 31, 2019)
524. First Amended Complaint, *People of California v. Purdue Pharma L.P., et al.*, Case No. 19STC19045 (Cal. Super. Ct. Los Angeles Cnty. Oct. 2, 2019)
525. First Amended Complaint, *State of Minnesota v. Purdue et al*., Case File No. 27-CV-18-10788
526. First Amended Complaint, *State of New York v. Purdue Pharma L.P.*, Index No. 400016/2018 (N.Y. Sup. Ct. Suffolk Cty.)
527. New York Municipalities' Master Long Form Complaint, *In re Opioid Litigation*, Index No. 400000/2017 (N.Y. Sup. Ct. Suffolk Cty.)

528. *In the Matter of Endo Solutions Inc. and Endo Pharm. Inc.*, Assurance No. 15-228 (Mar. 1, 2016)
529. Plaintiffs' Memorandum of Law in Opposition to Purdue, Teva, Cephalon, Watson, Actavis Pharma, Janssen, Endo, and Allergan Defendants' Joint Motion to Dismiss the Counties' Complaint for Failure to State a Cause of Action and, in Part, as Time-Barred, *In re Opioid Litigation*, Index No. 400000/2017 (N.Y. Sup. Ct. Suffolk Cty.), Dkt. No. 287
530. Plaintiff's Opposition to Individual Defendants' Motion to Dismiss for Lack of Personal Jurisdiction, Lack of Subject Matter Jurisdiction, and Failure to State a Claim, *State of Oregon v. Richard S. Sackler et al.*, No. 19CV22185 (Cir. Ct. Multnomah Cty.)
531. Plea Agreement and Exhibits thereto, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5
532. Plea Agreement and Exhibits thereto, *United States of America v. Purdue Pharma L.P.*, No. 2:20-cr-01028 (D.N.J. Nov. 24, 2020), ECF No. 6
533. Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories at 15-33, *People of the State of New York v. Purdue Pharma L.P., et al.*, Index No. 400016/2018 (Sup. Ct. Suffolk Cnty. Dec. 20, 2018)
534. February 4, 2014 Affidavit of Edward Mahony in *Purdue v. Hon. Steven Combs*, Case No. 2013-CA-001941-OA (Ky. Ct. App.)
535. March 26, 2019 Declaration of Jonathan Sackler in *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, No. 1884-cv-01808 (Mass. Sup. Ct. Suffolk Cnty.)
536. March 27, 2019 Declaration of Richard Sackler in *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, No. 1884-cv-01808 (Mass. Sup. Ct. Suffolk Cnty.)
537. March 28, 2019 Declaration of Beverly Sackler in *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, No. 1884-cv-01808 (Mass. Sup. Ct. Suffolk Cnty.)
538. March 28, 2019 Declaration of David Sackler in *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, No. 1884-cv-01808 (Mass. Sup. Ct. Suffolk Cnty.)
539. August 8, 2019 Declaration of Jonathan Sackler in *Consumer Protection Division Office of the Attorney General v. Purdue Pharma L.P.*, CPD Case No. 311366, OAH Case No. 1923474 (Md. Div. Cons. Prot.)
540. September 13, 2019 Declaration of Jonathan Sackler in *State of Colorado v. Purdue*, Case No. 18-CV-33300 (Colo. Dist. Ct., Denver Cty.)

D. <u>Other Discovery Materials From the Bankruptcy Cases</u>

541. Cecil Pickett Deposition Transcript, and exhibits thereto
542. Craig Landau Deposition Transcript, and exhibits thereto
543. David Sackler Deposition Transcript, and exhibits thereto
544. Ilene Sackler Deposition Transcript, and exhibits thereto
545. John Stewart Deposition Transcript, and exhibits thereto
546. Jonathan White Deposition Transcript, and exhibits thereto
547. Kathe Sackler Deposition Transcript, and exhibits thereto
548. Marianna Sackler Deposition Transcript, and exhibits thereto

549. Mark Timney Deposition Transcript, and exhibits thereto
550. Mortimer Sackler Deposition Transcript, and exhibits thereto
551. Peter Boer Deposition Transcript, and exhibits thereto
552. Richard Sackler Deposition Transcript, and exhibits thereto
553. Robin Abrams Deposition Transcript, and exhibits thereto
554. Steve Ives Deposition Transcript, and exhibits thereto
555. Stuart Baker Deposition Transcript, and exhibits thereto
556. Theresa Sackler Deposition Transcript, and exhibits thereto

E. Other Discovery Materials From Other Actions

557. Burt Rosen MDL Deposition Transcript
558. Craig McCann MDL Expert Report
559. Craig McCann MDL Supplemental Expert Report
560. Craig McCann MDL Second Supplement Expert Report
561. David Cutler MDL Deposition Transcript
562. David Kessler New York Deposition Transcript
563. Gerard Hevern MDL Expert Report
564. Jack Crowley MDL Deposition Transcript
565. James Rafalski MDL Expert Report
566. James Rafalski New York Expert Report
567. Lacey Keller MDL Deposition Transcript
568. Lacey Keller MDL Expert Report
569. Lee Ann Storey MDL Deposition Transcript
570. Lisa Miller Oklahoma Deposition Transcript
571. Meredith Rosenthal MDL Deposition Transcript
572. Meredith Rosenthal MDL Expert Report
573. Meredith Rosenthal MDL Daubert Opinion
574. Pamela Bennett MDL Deposition Transcript
575. Perry Fine Utah Deposition Transcript
576. Richard Sackler MDL Deposition Transcript
577. Richard Fanelli 30(b)(6) MDL Deposition Transcript
578. Sheila Weiss MDL Expert Report

F. Publicly Available Documents

579. 2/12/02 Transcript of Senate Hearing, Committee on Health, Education, Labor and Pensions, *available at* https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm
580. 11/22/19 Raymond-Side Informational Presentation, *available at* *https://www.judgeforyourselves.info/wp-content/uploads/2021/04/2021.04.08-Response-from-Side-B-Former-Directors-to-March-11-Letter.pdf*
581. 11/22/19 Raymond-Side Informational Presentation Supplemental Materials, *available at* *https://www.judgeforyourselves.info/wp-content/uploads/2021/04/2021.04.08-Response-from-Side-B-Former-Directors-to-March-11-Letter.pdf*

582. 1/15/20 Raymond-side Net Assets Report, *available at* *https://www.judgeforyourselves.info/wp-content/uploads/2021/04/2021.04.08-Response-from-Side-B-Former-Directors-to-March-11-Letter.pdf*
583. 2006 Percocet Label, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf
584. 2007 Massachusetts Medicaid Settlement
585. 2010 Percodan Label, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/007337s046lbl.pdf
586. 2014 Butrans FDA-Approved Label, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf
587. 2018 OxyContin FDA-Approved Label, *available at* https://www.fda.gov/media/131026/download
588. 2019 OxyContin FDA-Approved Label, a*vailable at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022272s043lbl.pdf
589. 2021 OxyContin FDA-Approved Label, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf
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592. *Anadarko Petroleum Co. v. Panhandle Eastern Corp.*, 545 A.2d 1171 (Del. 1988)
593. *Board of Directors Duties and Liabilities, available at* https://www.gsb.stanford.edu/sites/gsb/files/publication-pdf/cgri-quick-guide-03-board-directors-duties-liabilities.pdf
594. *Buprenorphine*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine
595. Cecil Pickett, Am. Assoc. for Cancer Research, https://www.aacr.org/governance/cecil-b-pickett-phd/
596. Cecil Pickett, Bloomberg, https://www.bloomberg.com/profile/person/4927281
597. *City of Newburgh v. Sarna*, 690 F. Supp. 2d 136 (S.D.N.Y. 2010), *aff'd in relevant part*, 406 F. App'x 557 (2d Cir. 2011)
598. Corporate Laws Committee, ABA Business Law Section, *Corporate Director's Guidebook – 6th Edition*, 66 BUS. LAW. 975 (2011)
599. DEA Suspicious Orders Report System, https://www.deadiversion.usdoj.gov/sors/index.html
600. *Douglas R. Jensen*, WHITE & CASE, https://www.whitecase.com/people/douglas-jensen
601. *Drug Scheduling*, DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/drug-scheduling
602. FDA, Timeline of Selected FDA Activities & Significant Events Addressing Opioid Misuse & Abuse, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm
603. *FDA approves abuse-deterrent labeling for reformulated OxyContin*, FDA News Release (Apr. 16, 2013), available at https://wayback.archive-

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606. FRANK H. EASTERBROOK & DANIEL R. FISCHEL, THE ECONOMIC STRUCTURE OF CORPORATE LAW (1991)
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608. HHS-OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003), *available at* https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf
609. *Hughes v. Hu*, 2020 WL 1987029 (Del. Ch. Apr. 27, 2020)
610. *In re Caremark Int'l., Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996)
611. Jonathan Kim and Marcel Bucsescu, *Greater Expectations: Strategies for Effective Board Meeting Preparation* (2018) at 2-3, *available at* https://millstein.law.columbia.edu/sites/default/files/content/images/5943_millstein_center_director_papers_-_greater_expectations.pdf.pdf
612. Judy Lewent, GLAXOSMITHKLINE, https://web.archive.org/web/20171123145759/https://www.gsk.com/en-gb/about-us/board-of-directors/judy-lewent/
613. Judy Lewent, Motorola Solutions, https://newsroom.motorolasolutions.com/executive-biographies/board-directors/judy-c-lewent.htm
614. *L.A. Grika on behalf of McGraw Hill Fin., Inc. v. McGraw*, 57 N.Y.S.3d 675, 2016 WL 8716417 (N.Y. Sup. Ct. 2016), *aff'd* 161 A.D.3d 450 (1st Dep't 2018)
615. *Mercier v. Inter-Tel (Del.), Inc.*, 929 A.2d 786 (Del. Ch. 2007)
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619. Press Release, Purdue Pharma, Purdue Pharma Statement on Massachusetts Complaint (Jan. 31, 2019), https://d279m997dpfwgl.cloudfront.net/wp/2019/01/purdue-statement-1-31.pdf
620. Ralph Snyderman, MD, DUKE UNIVERSITY SCHOOL OF MEDICINE, https://medicine.duke.edu/faculty/ralph-snyderman-md
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622. RESTATEMENT (THIRD) OF THE LAW OF AGENCY (2006)
623. *Samaritan Inns v. District of Columbia*, 1995 WL 405710 (D.D.C. June 30, 1995), *rev'd in part on other grounds*, 114 F.3d 1227 (D.C. Cir. 1997)
624. *Select Initiatives Addressing the Crisis*, PURDUE PHARMA, https://www.purduepharma.com/addressing-the-crisis/select-initiatives
625. Sept. 9, 2008 FDA Letter to Connecticut Attorney General Richard Blumenthal, FDA Docket No. FDA-2004-P-0294

626. *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362 (Del. 2006)
627. *Testimony of Dr. Craig Landau CEO of Purdue Pharma L.P.*, PURDUE PHARMA, https://www.purduepharma.com/wp-content/uploads/2020/12/Dr.-Landau-HCOR-Written-Testimony-FINAL.pdf
628. *T.V. Spano Bldg. Corp. v. Dep't of Nat. Res. & Env't Control*, 628 A.2d 53 (Del. 1993)
629. United States Sentencing Commission Guidelines Manual
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632. U.S. GEN. ACCOUNTING OFFICE, GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (2003)
633. U.S. GEN. ACCOUNTING OFFICE, GAO-12-115, PRESCRIPTION PAIN RELIEVER ABUSE; AGENCIES HAVE BEGUN COORDINATING EDUCATION EFFORTS, BUT NEED TO ASSESS EFFECTIVENESS (2011)
634. *U.S. v. Park*, 421 U.S. 658 (1975)
635. 1 WILLIAM E. KNEPPER & DAN A. BAILEY, LIABILITY OF CORPORATE OFFICERS AND DIRECTORS (8th ed. 2014)
636. 6 Del. C. §15-306
637. 6 Del. C. §17-303
638. 6 Del. C. § 17-403
639. 21 C.F.R. §314.80

G. Other

640. To the extent not identified above, any other documents referenced in the Statement of Assumed Facts and in the Expert Report.

EXHIBIT C TO THE EXPERT REPORT OF LAWRENCE HAMERMESH

STATEMENT OF ASSUMED FACTS[1]

I. PURDUE AND THE SACKLER FAMILIES

A. *Purdue Pharma L.P. and Purdue Pharma, Inc.*

1. Purdue Pharma L.P. ("**PPLP**") is a Delaware limited partnership. Purdue Pharma, Inc. ("**PPI**") is a New York corporation. Together, PPLP and PPI are **Purdue**.[2]

2. PPI, is, and throughout the Relevant Period was, the general partner of PPLP.[3] As the general partner of PPLP, throughout the Relevant Period, PPI had "sole responsibility for managing and operating the business of [PPLP]."[4]

3. PPLP's business was substantial. For much of the Relevant Period, PPLP had between 1,000 and 1,600 plus employees.[5] These employees worked in different departments,

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[1] The following Statement of Assumed Facts ("**SAF**") was prepared by counsel. It focuses primarily on the period from June 1, 2007 through December 2018 (the "**Relevant Period**"). To the extent that this SAF references certain allegations made by claimants, those allegations are referenced only for the fact of the allegations—as examples of allegations made—not the truth of those allegations. Except where otherwise noted, citations in this SAF are to evidence that has been taken in, filed in, produced in, or from these bankruptcy cases, including the documentary and testimonial evidence from the National Opiate Multi-District Litigation that has been produced again in these cases.

[2] Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories at 11, *People of the State of New York v. Purdue Pharma L.P., et al.*, Index No. 400016/2018 (Sup. Ct. Suffolk Cnty. Dec. 20, 2018).

[3] Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories at 11, *People of the State of New York v. Purdue Pharma L.P., et al.*, Index No. 400016/2018 (Sup. Ct. Suffolk Cnty. Dec. 20, 2018). *See also* Amended and Restated Limited Partnership of PPLP Agreement dated as of January 2, 1997 ("**2nd PPLP Partnership Agreement**") (PDD9316726090); Third Amended and Restated Limited Partnership of PPLP dated as of March 7, 2018 ("**3rd PPLP Partnership Agreement**") (PUT000010556).

[4] 2nd PPLP Partnership Agreement (PDD9316726090) at §12(a); 3rd PPLP Partnership Agreement (PUT000010556) at §12(a).

[5] *See* 1Q 2008 Board Report (PPLP004367134) at -156 (1,199 total employees); 1Q 2009 Board Report (PPLP004367262) at -289 (1,367 total employees); 2Q 2010 Board Report

including departments dedicated to manufacturing, research and development, and compliance, and a general counsel's office.[6]

4. Purdue manufactures prescription opioids, which are a class of drugs used to reduce pain and treat moderate to severe pain.

5. The prescription opioid industry is highly regulated. Most opioid pain medications approved by the FDA are Schedule II drugs. Unlike Schedule I drugs, which are illegal and deemed by the DEA to have "no currently accepted medical use and a high potential for abuse," Schedule II medications have a legitimate medical purpose but have a "high potential for abuse" which may lead to "severe psychological or physical dependence."[7] Schedule III medications—like testosterone, codeine and Purdue's transdermal opioid patch, Butrans— are drugs with "a moderate to low potential for physical and psychological dependence."[8]

6. One of the prescription drugs manufactured by Purdue is OxyContin. In 1995, the FDA approved OxyContin as a Schedule II drug. Every FDA-approved OxyContin label from 1995 through today reflects the FDA's determination that OxyContin is safe and effective for the

(PPLP004367018) (1,417 total employees) at -045; 1Q 2011 Board Report (PPLPC012000322426) at -461 (1,636 total employees); 1Q 2012 Board Report (PPLPC012000374791) at -823 (1,644 total employees); 4Q 2013 Board Report (PPLPC002000181035) at -081 (1,690 total employees). The number diminished substantially after Purdue voluntarily stopped promoting opioids in February 2018 and terminated its opioid medication sales force. Debtors' Informational Brief (ECF No. 17) at 32.

[6] *See, e.g.*, 3Q 2013 Board Report (PPLPC002000186911) at –965 (reflecting over 1,700 employees).

[7] *See Drug Scheduling*, DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/drug-scheduling.

[8] *Id.*

treatment of pain.[9] The FDA-approved label has always prominently warned that OxyContin is subject to abuse and diversion.[10]

7. Since 2001, the FDA-approved label for OxyContin has included a black-box warning, explicitly warning that OxyContin has "an abuse liability similar to morphine" and "can be abused in a manner similar to other opioid agonists, legal or illicit."[11] "A boxed warning is the most serious warning placed in the labeling of a prescription medication."[12] The OxyContin label has continuously warned that "Oxycodone, like morphine and other opioids used in analgesia, can be abused and is subject to criminal diversion."[13]

8. During the Relevant Period, Purdue developed an abuse-deterrent formulation of OxyContin ("**ADF OxyContin**") to "[m]ake OxyContin less abusable, less desirable for abusers, and decrease diversion events."[14]

9. When Purdue launched ADF OxyContin in April 2010, the FDA-approved label did not describe its abuse deterrent properties.

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[9] *See* 1995 OxyContin FDA-Approved Label (PPLPC044000064536) at -536; 2019 OxyContin FDA-Approved Label at 1, a*vailable at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022272s043lbl.pdf.

[10] *See, e.g.*, 1995 OxyContin FDA-Approved Label (PPLPC044000064536) at -537 ("Oxycodone products are common targets for both drug abusers and drug addicts. … [C]are should be taken to prevent diversion or abuse by proper handling.").

[11] 2001 OxyContin FDA-Approved Label (PDD1501070063) at -063.

[12] Sept. 9, 2008 FDA Letter to Connecticut Attorney General Richard Blumenthal at 2, FDA Docket No. FDA-2004-P-0294.

[13] 2001 OxyContin FDA-Approved Label (PDD1501070063) at -069.

[14] 6/12/12 Email from William Mallin with Attachment (PPLPC057000011188) at -194, slide 3.

10. The FDA approved a revised label in April 2013 stating that the ADF formulation "has physicochemical properties expected to make abuse via injection difficult" and "to reduce abuse via the intranasal route," although abuse "by the oral route is still possible."[15]

11. In addition to OxyContin, Purdue manufactures other products, including Butrans, a Schedule III seven-day, transdermal patch pain opioid, which was approved by the FDA in 2010, and Hysingla, a Schedule II extended release opioid, which was approved by the FDA in 2014.[16]

B. ***Ownership of Purdue and Other Pharmaceutical Companies***

12. Purdue is beneficially owned by two branches of the Sackler family: the Raymond Sackler family, consisting of the descendants of Raymond Sackler and their current and former spouses (also known as "**Side B**"), and the Mortimer Sackler family, the descendants of Mortimer Sackler (also known as "**Side A**") and their current and former spouses (collectively, Side A and Side B are the "**Sackler families**"). The Raymond Sackler family includes Beverly Sackler (Raymond's wife), Richard and Jonathan Sackler (Raymond's sons), and David Sackler (Richard's son). Beverly Sackler died in 2019 and Jonathan Sackler died in 2020.

13. The Raymond Sackler family and the Mortimer Sackler family each have an indirect fifty percent ownership interest in Purdue.

14. The PPI Certificate of Incorporation provided for the issuance of 1,000 PPI shares with a par value of one dollar, to be divided into two classes of 500 shares each, called Class A

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15 2013 OxyContin FDA-Approved Label (PPLPC003000060503) at -525.

16 Debtors' Informational Brief (ECF No. 17) at 8.

and Class B.[17] The Class A PPI shares are indirectly, beneficially owned by the Mortimer Sackler family. The Class B PPI shares are indirectly, beneficially owned by two Side B trusts.

15. Half (250) of the Class B PPI shares—that is, 25% of the PPI shares—have been held by Perthlite Holdings LLC.[18] Perthlite Holdings LLC is owned by the Raymond R. Sackler Trust 2B dated 12/23/89 Trust (the "**2B Trust**"), which is a discretionary and irrevocable trust for the benefit of the issue of Jonathan Sackler.[19] Jonathan Sackler was not a beneficiary of the 2B Trust. [20] Jonathan Sackler did not serve as a trustee of the 2B Trust during the Relevant Period, but he had the right to resume the office of trustee of the 2B Trust to remove a successor trustee.[21]

16. Half (250) of the Class B PPI shares—that is, 25% of the PPI shares—have been held by Linarite Holdings LLC.[22] Linarite Holdings LLC is owned by the Raymond R. Sackler Trust 1B dated 12/23/89 Trust (the "**1B Trust**"), which is a discretionary and irrevocable trust for the benefit of the issue of Richard Sackler.[23] Richard Sackler has not been a beneficiary of the 1B Trust. [24] Richard Sackler did not serve as a trustee of the 1B Trust during the Relevant

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17 *See* Certificate of Amendment of Certificate of Incorporation of PPI dated July 30, 2012 ("**Amendment of Certificate of Incorporation**") (PPLP004415886) at -888–90.

18 *See* 1/21/10 Amendment to Shareholder Agreement (PPLP004415716); 11/22/19 Raymond-Side Informational Presentation at 79.

19 11/22/19 Raymond-Side Informational Presentation at 29, 79.

20 *Id.* at 29.

21 *Id.*

22 *See* 1/21/10 Amendment to Shareholder Agreement (PPLP004415716); 11/22/19 Raymond-Side Informational Presentation at 78.

23 11/22/19 Raymond-Side Informational Presentation at 28, 78.

24 *Id.* at 28.

Period, but he had the right to resume the office of trustee of the 1B Trust to remove a successor trustee.[25]

17. Throughout the Relevant Period, PPLP was beneficially owned by trusts for the benefit of the Sackler family[26]:

- At the start of the period, PPLP was 99.75% owned by a United Kingdom partnership called IRC 1466 Withholding Partnership L.P. and 0.25% owned by PPI. IRC 1466 Withholding Partnership L.P. was beneficially owned by trusts for the benefit of members of the Sackler family.[27]
- From December 31, 2008 to April 30, 2010, PPLP was owned 99.5061% by PLP Associates Holdings L.P., 0.2464% by PLP Associates Holdings Inc. and 0.2475% by PPI. PLP Associates Holdings L.P. and PLP Associates Holdings Inc. were beneficially owned by trusts for the benefit of members of the Sackler families.[28]
- From April 30, 2010 until the end of the Relevant Period, PPLP was 100% owned by Purdue Holdings, L.P., a Delaware limited partnership. Purdue Holdings L.P. was beneficially owned by trusts for the benefit of members of the Sackler families.[29]

18. In addition, to Purdue, Side A and Side B also indirectly, beneficially own a number of other pharmaceutical companies.

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25 *Id.* at 28.

26 Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories at 11-13, *People of the State of New York v. Purdue Pharma L.P., et al.*, Index No. 400016/2018 (Sup. Ct. Suffolk Cnty. Dec. 20, 2018).

27 *Id.* at 12.

28 *Id.* at 12-13.

29 *Id.* Purdue Holdings, L.P. is now known as Pharmaceutical Research Associates L.P. *Id.* at 13.

19. Throughout the Relevant Period, Side A and Side B both had an indirect 50% ownership interest in Rhodes Pharmaceuticals L.P. ("**Rhodes Pharma**") and related entities (together, "**Rhodes**"), which from January 1, 2008, until May 2019 were owned separately from Purdue.[30] Additionally, Side A and Side B each had a 50% ownership in a number of foreign pharmaceutical companies referred to as the Independent Affiliated Companies or "IACs."[31]

20. Members of the Sackler families—who were the indirect beneficial owners—periodically received presentations to keep them informed about the businesses.[32] These beneficiary presentations provided high-level updates designed to provide "an opportunity for Sackler family members who were not serving on the board to gain some level of understanding for what was going on with the businesses."[33]

21. No evidence has been adduced that any of the beneficiaries engaged in management of Purdue at any of those meetings.[34]

22. The IACs were managed separately from Purdue. The IACs were advised, when they requested advice, by the board of MNP Consulting Ltd., on which sat a number of members of the Sackler families and prominent outside industry experts, and which provided recommendations to the different IACs.[35]

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30 Debtors' Informational Brief (ECF No. 17) at 10-11.

31 1/15/20 Raymond-side Net Assets Report at 15.

32 *See, e.g.*, 5/18/11 Beneficiaries Presentation (PPLPC037000098187); 11/3/11 Beneficiaries Presentation (PPLPC034000597805); 11/3/12 Beneficiaries' Meeting Book (PPLP004409088); 11/16/13 Beneficiaries' Meeting Book (PPLPC051000193984).

33 Craig Landau Dep. Tr. at 302:10-17.

34 *See, e.g.*, Marianna Sackler Dep. Tr. at 111:20-112:12, 114:3-118:2, 120:21-121:9 (testimony regarding beneficiary meetings).

35 *See* David Sackler Dep. Tr. at 76:14-77:5.

23. At least one document produced during these proceedings appears to be decisions by the MNP Board about Purdue.[36] It is the testimony of Stuart Baker—longtime outside counsel and adviser to the Sackler families; an officer of PPI, PPLP and MNP; an officer and/or director of certain IACs; and the person who chaired meetings of the PPI and MNP Boards—that this document was a mistake and that the MNP Board did not make decisions about Purdue.[37]

24. Multiple witnesses testified that MNP was separate from Purdue and did not make decisions about Purdue.[38]

II. PPI'S BOARD

25. During the Relevant Period, no member of the Sackler families was a member of Purdue's management.[39]

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[36] Stuart Baker Dep. Ex. 26.

[37] Stuart Baker Dep. Tr. at 332:10-12 ("I see that and I'm telling you that as I sit here today and look at it, it's a mistake."); *see generally id.* at 330:5-334:7; 306:25-307:18; Stuart Baker Dep. Ex. 24 at Ex. B.

[38] *See e.g.*, Stuart Baker Dep. Tr. at 337:2-3 ("MNP had no function with regard to Purdue."); Kathe Sackler Dep. Tr. at 208:10-15 ("[Q.] Did the MNP Board provide recommendations to the Purdue Board? [A.] No. The MNP Board only reviewed matters and provided recommendations to the international Independent Associated Companies, not the U.S. Purdue companies."); Theresa Sackler Dep. Tr. at 394:21-395:2 ("[Q.] Did MNP play a role in determining when funds should be distributed from Purdue to the IACs? … [A.] Not that I recall."); D. Sackler Dep. Tr. at 76:14-17 ("From time to time during your service as a director at MNP, did MNP make recommendations to the board of Purdue? A.· I don't recall."); Cecil Pickett Dep. Tr. at 91:23-92:3 ("So in your mind, there were two separate board meetings; there was the Purdue PPI US entity and then the MNP international entities?· A· That's what I recall, yes."); Craig Landau Dep. Tr. at 286:9-19 ("At the time my understanding was that the – there was a Purdue board that was … the governance body for the Purdue US business and not any other board, including the MMP [*sic*] board, if you will.").

[39] Purdue's Responses and Objections to Plaintiff's First Set of Interrogatories at 15-33, *People of the State of New York v. Purdue Pharma L.P., et al.*, Index No. 400016/2018 (Sup. Ct. Suffolk Cnty. Dec. 20, 2018) at 15-33. *See also* Mar. 28, 2019 Beverly Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.); Mar. 27, 2019 Richard Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.); Mar. 26, 2019 Jonathan Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No.

26. During the Relevant Period, a number of Sackler family members served on PPI's Board of Directors, including on Side B: Richard, Jonathan, Beverly and David Sackler.[40]

27. Beverly Sackler served on PPI's Board of Directors from January 15, 1993 until October 17, 2017. Richard Sackler served on PPI's Board of Directors from October 2, 1990 until July 24, 2018. Jonathan Sackler served on PPI's Board of Directors from October 2, 1990 until December 8, 2018. David Sackler served on PPI's Board from July 19, 2012 until August 14, 2018.

28. During the Relevant Period, none of the Side B directors held any role at PPI other than his or her role as director, and none had any role at PPLP at all.[41]

29. During the Relevant Period, one member of Side B, Marianna Sackler (one of Richard's children), held a part-time position in Purdue's medical research and development department for four months in late 2009 and early 2010.[42] She was not part of Purdue's management. No evidence has been adduced linking her personal conduct to the Claims. In the pre-petition litigation, Marianna Sackler was named in just one lawsuit: that brought by the California Attorney General. The complaint filed in that action alleged no facts linking her conduct to any wrongdoing or alleged cause of action. *See* First Amended Complaint, *People of*

1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.); Mar. 28, 2019 David Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.).

40 PPI Board of Directors List (PPLPUCC500140094).

41 Mar. 28, 2019 Beverly Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.); Mar. 27, 2019 Richard Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.); Mar. 26, 2019 Jonathan Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.); Mar. 28, 2019 David Sackler Decl. at ¶3, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty.).

42 Marianna Sackler Dep. Tr. at 30:14-18, 39:8-11.

the State of California v. Purdue Pharma L.P., Case No. 19STCV19045 (Cal. Super. Ct., L.A. Cty. Oct. 2, 2019).

30. According to the PPI By-Laws, the PPI Board's authority was reserved to "[a]ll substantive matters not in the day-to-day ordinary course of business."[43] The "matters reserved to the Board" include certain material issues enumerated in the By-Laws, such as approval of budgets; introduction of new products; product and intellectual property rights acquisitions costing more than 1% of gross margin of the acquiring entity; and election, engagement, compensation, and termination of senior officers.[44]

31. Under the PPI By-Laws, matters regarding Purdue's day-to-day business were to be managed by Purdue's management. This is consistent with a Purdue document describing its governance process, which provides that, "Purdue operates its business under the direction of the Purdue management team subject to Board approval of (1) Annual Budget, (2) Business Development Opportunities/Investments, (3) Financings, (4) Facilities decisions.").[45]

32. The PPI By-Laws also provided that "[a]ll Corporation [*i.e.*, PPI] and Partnership [*i.e.*, PPLP] executives shall report to the President and CEO, except for matters related to the shareholders, Board of Directors or its Committees, where the Executive Vice President, Counsel to the Board [Stuart Baker] shall report as otherwise agreed."[46] The By-Laws charged the President and CEO with "ensur[ing] that the Board of Directors receives all information necessary on a current basis in order to enable the Board of Directors to be informed of all major

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43 *See* PPI By-Laws (PUT000010519) at -548.

44 *See id.* at -548.

45 Governance Process (PPLPUCC9003577789).

46 *See* PPI By-Laws (PUT000010519) at art. III, § 5(ii)(A); Baker Ex. 24 at Ex. B, p. 1.

events and matters that alone or in the aggregate would have a material effect on the business, assets, operations or condition, financial or otherwise, or prospects of the Partnership."[47]

33. A 2012 Purdue presentation describing Purdue's structure explained that

> Under the direction of the Board, the Executive Committee is the primary governance and decision-making body at Purdue. The Executive Committee sets overall product and organizational direction and strategy (including identifying new therapeutic areas to enter, product development and acquisition opportunities to pursue and significant changes to business processes), and devises and oversees processes to manage critical events.[48]

No member of the Sackler family sat on the Executive Committee during the Relevant Period.

34. During the Relevant Period, half of PPI's directors were appointed by the Class A PPI shareholders (the "**Class A Directors**") and half by the Class B PPI shareholders (the "**Class B Directors**").[49]

35. The PPI Certificate of Incorporation required a quorum "of not less than one-third of the entire [PPI] Board" "for the transaction of any and all business of the Board," provided that such quorum must include a specified minimum presence of Class A and B Directors.[50] The PPI By-Laws also stated that the PPI Board should "strive to achieve unanimity in its decisions."[51] However, if unanimity could not be achieved, the PPI Certificate of Incorporation

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47 *See* PPI By-Laws (PUT000010519) at art. III, § 5(ii)(C).

48 May 2012 Presentation (PPLPC012000378037) at slide 5.

49 The PPI Certificate of Incorporation provided that Class A and Class B shares each "shall vote separately as a class in connection with the election of [PPI] Directors." *See* Amendment of Certificate of Incorporation (PPLP004415886) at -888-89; Amendments to By-Laws of April 18, 2008 ("**Amendments to By-Laws**") (PPLP004415363) at -370 (amending art. IX, §2(ii)).

50 *See* Amendment of Certificate of Incorporation (PPLP004415886) at -888-889 (amending art. III). *See also* Amendments to By-Laws (PPLP004415363) -371 (amending art. IX, § 3(i)(A)).

51 *See* PPI By-Laws (PUT000010519) at art. III, § 5(i)(C).

specified that "[a]ll actions by the Board … shall be approved by" a majority of the Class A Directors and a majority of the Class B Directors present at the meeting.[52]

36. During the Relevant Period, the PPI Board included at least 5 Class B Directors and at least 4 Class A Directors:[53]

YEAR	TOTAL CLASS B DIRECTORS	TOTAL CLASS A DIRECTORS	TOTAL DIRECTORS
2007	4	5	9
2008	from 4 to 6	5	from 9 to 11
2009	5	from 5 to 6	from 10 to 11
2010	5	from 6 to 7	from 11 to 12
2011	5	6	11
2012	from 5 to 8	6	from 11 to 14
2013	8	6	14
2014	8	from 5 to 6	from 13 to 14
2015	8	5	13
2016	8	from 5 to 6	from 13 to 14
2017	from 5 to 8	6	from 11 to 14
2018	from 2 to 5	from 2 to 6	from 4 to 11

37. The PPI directors did not always agree.

38. Outside Director Cecil Pickett testified: "sometimes there were differences between the family members … disagreements within families and within the family members, both sides of the family." C. Pickett Dep. Tr. at 140:25-141:6.

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52 *See* Restated Certificate of Incorporation of PPI as of March 4, 2003 (PKY180173691) at art. III; Amendment of Certificate of Incorporation (PPLP004415886) at -888-89 (amending art. III). *See also* Amendments to By-Laws (PPLP004415363) at -373 (amending art. IX, § 3(i)(B)).

53 PPI Board of Directors List (PPLPUCC500140094).

39. In one 2009 email from Richard Sackler (Side B) to Mortimer Sackler (Side A), regarding Mortimer's opposition to acquiring a business (Remoxy) at cash value, Richard wrote: "I see your point of view. Maybe I don't agree with it, but I see it."[54]

40. In 2014, David Sackler (Side B) wrote to his father, Richard Sackler, and uncle Jonathan Sackler (Side B) regarding Side A's refusal to approve pursuit of an acquisition of a company named Igenica: "The Mortimer family's refusal to take on that project was horrible. . . ."[55]

41. In 2014 and 2015, those directors had lengthy disagreements about the wisdom of distributions from or reinvestment into Purdue.

42. Outside Director Cecil Pickett testified: "The A side probably was more supportive of more distributions; where the B side was more supportive of putting money back in the company." Cecil Pickett Dep. Tr. at 143:3-7.

43. In November 2014, Jonathan Sackler informed the Board that Side B opposed further distributions that year, and explained that it "prefer[red] to leave the remaining cash in the business." In that email, he discussed the differing investment philosophies of Side A and Side B.[56]

44. In a June 2015 email sent by Steve Ives (a longtime Side B advisor), acting as a representative of Side B, to a representative of Side A, Mr. Ives, urged that "cash distributions … be tempered," and expressed Side B's desire to have "the lowest acceptable amount of cash coming out of the company." [57]

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54 5/19/09 E-mail from Richard Sackler to Mortimer Sackler (PPLPC061000044237).

55 10/7/14 Email from David Sackler to Jonathan Sackler (PPLPUCC002907060).

56 11/15/14 Email from Jonathan Sackler (RSF_OLK00040227) at -231.

57 6/26/15 Email from Stephen Ives (RSF_OLK00021303) at 305-06.

45. In 2015, Side B made a subordinated debt proposal, under which Purdue would make a distribution to both sides of the family, and then Side B would loan back to Purdue the full amount of its distribution in return for subordinated debt, in order to keep cash in Purdue. In June 2015 discussions with the Side A directors, Side B "push[ed] the notion of sub debt as a means of putting both families on equal footing as to their fundamental desires (cash distributions on one hand and strengthening the business on the other)."[58] In August 2015, Side B drafted terms for its subordinated debt offer.[59] Side B's offer to take on subordinated debt was not agreed to by Side A.

46. Side B Directors did not always agree among themselves. In 2014, Class B Directors Richard Sackler and David Sackler voted in favor of a proposed acquisition of Rye Pharmaceuticals, which Class B Director Jonathan Sackler opposed.[60]

47. In 2016, Jonathan Sackler and David Sackler voted in favor of a proposed deal involving Exicure, while Richard Sackler voted against it.[61]

48. During the relevant period, several distinguished non-family members served on the PPI Board. They included:[62]

- **Ralph Snyderman MD**, the Former Chancellor for Health Affairs and Former Dean of the Medical School of Duke University. Dr. Snyderman had served on the boards of numerous other pharmaceutical and biotech companies, including Trevena, Inc., Targacept, Liquida Technologies, CareDx, Inc. and Procter & Gamble Company.[63]

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58 *Id*. at -306.

59 8/13/15 Email from David Sackler (RSF_OLK00021534). *See also* 7/13/15 Email from Stephen Ives with Attachment (RSF00471979) (attaching draft subordinated debt term sheet).

60 Notes of October 2014 PPI Board meeting (PPLPBN-00002063) at -090.

61 Notes of October 2016 PPI Board meeting (PPLPBN-00002815) at -834.

62 PPI Board of Directors List (PPLPUCC500140094).

63 Ralph Snyderman, MD, DUKE UNIVERSITY SCHOOL OF MEDICINE, https://medicine.duke.edu/faculty/ralph-snyderman-md (last visited June 10, 2021); Ralph

- **Judy Lewent**, the former CFO of Merck & Co. and the former President of Merck's Human Health Asia Division. Ms. Lewent had also served on the boards of numerous technology, food, and health science companies, including Dell Inc., Quaker Oats Company, Motorola Inc., Motorola Solutions Inc., Thermo Fisher Scientific Inc., and GlaxoSmithKline PLC.[64]

- **Cecil Pickett**, a former Corporate Senior Vice President of Schering-Plough Corp., Senior Vice President and President of Schering-Plough Research Institute. Mr. Pickett had also served on the boards of Idec Pharmaceuticals Corp. and Biogen Idec Inc.[65]

- **Peter Boer**, the President and CEO of Tiger Scientific Inc. Mr. Boer was a former executive at W.R. Grace & Co., and has also served as a director of W.R. Grace & Co., NOVA Chemicals Corporation, ENSCO, Inc., and Chomerics, Inc.[66]

- **Paulo Costa**, the former President of Janssen Pharmaceutica, Inc. US, the Executive Vice President of Global Franchise Development, of Johnson & Johnson, and the President and CEO of Novartis Pharmaceuticals Corporation. He also served as the Chairman of the board of Amylin Pharmaceuticals, Inc. and was a member of the board of MacroGenics, Inc.[67]

49. There is no evidence that any of these non-family members took issue with Purdue's compliance, anti-diversion or marketing programs. Two of these directors were

Snyderman, M.D., iRhythm, https://investors.irhythmtech.com/board-member/ralph-snyderman-md (last visited June 7, 2021).

[64] Judy Lewent, GLAXOSMITHKLINE, https://web.archive.org/web/20171123145759/https://www.gsk.com/en-gb/about-us/board-of-directors/judy-lewent/; Judy Lewent, Motorola Solutions, https://newsroom.motorolasolutions.com/executive-biographies/board-directors/judy-c-lewent.htm (last visited June 7, 2021).

[65] Cecil Pickett, Am. Assoc. for Cancer Research, https://www.aacr.org/governance/cecil-b-pickett-phd/ (last visited June 7, 2021); Cecil B. Pickett, Bloomberg, https://www.bloomberg.com/profile/person/4927281 (last visited June 7, 2021).

[66] About F. Peter Boer, Tiger Scientific Inc., http://www.boer.org/bio.shtml (last visited June 7, 2021); Peter Boer Dep. Ex. 1 (F. Peter Boer, Curriculum Vitae (PPLPUCC9003818077)).

[67] Paulo Costa, MacroGenics, http://ir.macrogenics.com/board-directors/paulo-costa (last visited June 7, 2021); Paulo Costa, Twst.com, https://www.twst.com/bio/paulo-costa/ (last visited June 7, 2021).

deposed in this action and neither of them testified that they believed that the Sackler members of the Board were acting improperly.[68]

A. *Allegations that PPI's Board was the* "De Facto" *CEO of Purdue*

50. Some Claimants have alleged that the PPI Board acted as the "'*de facto*' CEO" of Purdue.[69]

51. This contention is based on a phrase—"the Board of Directors [is] serving as the 'de facto' CEO"[70]—taken out of context from a memorandum prepared by Craig Landau (when he was President of Purdue Canada, which is a foreign IAC) for the board of MNP.[71]

52. The MNP board advised the IACs in 49 countries outside the U.S.—including Purdue Canada[72]—but not PPLP or PPI.

53. Landau's memo does not address PPLP, PPI, or the role of PPI's Board or MNP's relationship with Purdue. It was one of several memos prepared in connection with a strategy session on the global pharmaceutical businesses of the Sackler families. All of the memos, including Landau's, proposed a global CEO to relieve the MNP Board.[73]

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68 *See* F. Peter Boer Dep. Tr.; Cecil Pickett Dep. Tr.

69 *See, e.g.*, First Amended Complaint ¶485, *Commonwealth of Massachusetts v. Purdue Pharma, L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty. Jan. 31, 2019) ("MA AG FAC").

70 *Id*.

71 5/5/17 Email from Craig Landau (PWG004670879) at -880 (discussing "global investment strategy"); Landau Dep. Tr. at 329:19-330:4 ("It was my understanding that [the memo] would … ultimately … make its way to the board of directors. … [I]t would be the MNP board.").

72 *See, e.g.*, Landau Dep. Tr. 295:12-15 ("Q. Who did you report to as CEO of Purdue Canada? A. My understanding was that I reported to the MNP board."); 12/7/16 MNP Consulting Limited Board Agenda (PPLPUCC9002689883) at -038 (proposed decision by MNP Board concerning Purdue Canada budget).

73 *See, e.g.*, 5/5/17 Memo From Mark Timney (PPLPC051000317758) at -763-64; 5/15/17 Memo From Raman Singh (PPLPC051000317750) at -752-53; 2017 Memo to Ake Wikstrom (PPLPC051000317768) at -772.

54. At the time, Purdue had its own CEO, Mr. Timney, an experienced pharmaceutical official who had previously worked in senior executive positions at Merck & Co.

III. THE 2007 GUILTY PLEA AND RELATED SETTLEMENTS

55. When OxyContin was launched in 1996, the FDA held the view that extended release opioids, like OxyContin, were less likely to be abused than other prescription opioids.[74] One FDA official testified before Congress in 2002 that:

> [A]t the time of its approval, FDA believed that the controlled-release characteristics of the OxyContin formulation would result in less abuse potential since, when taken properly, the drug would be absorbed slowly and there would not be an immediate 'rush' or high that would promote abuse.[75]

This view was the medical consensus at the time—that extended release opioids were less likely to be abused than other opioids.[76]

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[74] *See* FDA, Timeline of Selected FDA Activities & Significant Events Addressing Opioid Misuse & Abuse, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm.

[75] *See* 2/12/02 Transcript of Senate Hearing, Committee on Health, Education, Labor and Pensions at 16, *available at* https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm ("At the time of its approval, FDA believed that the controlled-release characteristics of the OxyContin formulation would result in *less* abuse potential since, when taken properly, the drug would be absorbed slowly and there would not be an immediate 'rush' or high that would promote abuse.") (emphasis added).

[76] *See, e.g.*, Harriet de Wit, et al., *Rate of Increase of Plasma Drug Level Influences Subjective Response in Humans*, PSYCHOPHARMACOLOGY 107:352, 358 (1992) (PKY181753181) at -187 ("pharmacological agents and drug formulations with relatively slower onset would clearly have a lower potential for abuse than those with faster onset."); William H. Oldendorf, *Some Relationships Between Addiction and Drug Delivery to the Brain*, NIDA RESEARCH MONOGRAPH 120:13 (1992) (PKY181870332) at -332 (observation that the "more immediate the effect after intake, the more addicting the substance is likely to be … has been widely discussed in the literature and is not presented here as novel") (emphasis added); Daniel Brookoff, *Abuse Potential of Various Opioid Medications*, 8 J. GEN. INTERN. MED. 688, 690 (1993) (PPLPC013000157356) at -359 ("This suggests that the controlled-release opioid formulations may have a lower potential for abuse than do other narcotic medications.") (emphasis added); *id*. at -357, nn. 9 & 10 ("In some emergency departments, controlled-release formulations have become the analgesics of choice due to physicians' perceptions that they are rarely abused.").

56. Consistent with the consensus, early versions of the FDA-approved OxyContin label stated: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."[77]

57. In 2001, "[r]eports of illegal misuse, abuse and diversion of OxyContin® … prompted" Purdue, with the FDA's approval, to revise OxyContin's label, adding the black box warnings about the risks associated with OxyContin use, and eliminating certain statements about the benefits of OxyContin, including statements to the effect that it was believed that OxyContin would be less subject to abuse.[78]

58. In 2002, the U.S. Attorney's Office for the Western District of Virginia began an investigation into Purdue's sales and marketing practices relating to OxyContin. In 2007, The Purdue Frederick Company, Inc. ("**Purdue Frederick**") pled guilty to felony misbranding of OxyContin (the "**2007 Guilty Plea**"), three Purdue Frederick executives pled guilty to strict liability misdemeanor misbranding charges, and Purdue Frederick settled related civil claims (collectively, the "**2007 Federal Settlement**"). The federal investigation lasted five years and examined the conduct of Purdue and its executives—including the members of the Sackler Families who served on the PPI Board (the "**Former Directors**")—from late 1995 to May 2007.

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[77] *See* 1995 OxyContin FDA-Approved Label (PPLPC044000064536). Prior FDA-approved labels for Percocet and Percodan—two non-Purdue Schedule II medicines containing oxycodone—contained similar statements in line with this consensus that, "Opioid addiction is relatively rare in patients with chronic pain but may be more common in individuals who have a past history of alcohol or substance abuse or dependence." *See* 2010 Percodan Label at pdf p. 17, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/007337s046lbl.pdf; 2006 Percocet Label at pdf p. 2, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf.

[78] 7/18/01 Purdue Dear HCP Letter (PDD1715240425) at -425; *see also* 2001 OxyContin FDA-Approved Label (PDD1501007063).

The misconduct that was admitted in the 2007 Guilty Plea ended by June 30, 2001. No Sackler family members were named, much less charged, as participants in any misconduct.[79]

59. In the Agreed Statement of Facts accompanying the plea, Purdue admitted that, until on or about June 30, 2001, "certain Purdue supervisors and employees, with the intent to defraud or mislead" healthcare professionals committed multiple acts of deception and misconduct in connection with OxyContin marketing.[80]

60. Purdue entered into a five-year Corporate Integrity Agreement ("**CIA**") with the Office of the Inspector General ("**OIG**") of the U.S. Department of Health and Human Services ("**HHS**").[81] The CIA was designed to assure Purdue's compliance with federal healthcare law, including all statutes, regulations and written directives of the FDA, Medicare, Medicaid and all other federal healthcare programs.[82] The CIA obliged Purdue, *inter alia*, to (i) appoint a Compliance Officer to "be responsible for monitoring the day-to-day compliance activities engaged in by Purdue" and to make quarterly reports to the Board, and (ii) appoint a Corporate Compliance Council composed of the Compliance Officer and members of senior management charged with "support[ing] the Compliance Officer in fulfilling his/her responsibilities (*e.g.*, shall assist in the analysis of the organization's risk area and shall oversee monitoring of internal and external audits and investigations)."[83]

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79 *See* Information and Attachment B thereto, *United States* v. *The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-2 ("**2007 Agreed Statement of Facts**").

80 2007 Agreed Statement of Facts at ¶20 (capitalization omitted); *see also id.*at ¶¶21-43.

81 *See* Information, Attachment E, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-5 (CIA).

82 CIA § I, first paragraph.

83 *Id*. at 4-5.

61. The CIA also required that Purdue (1) establish policies to ensure that (a) the promotion of Purdue's products met all applicable FDA and federal healthcare program requirements and (b) design its compensation practices "to ensure that financial incentives do not inappropriately motivate [Relevant Covered Persons] to engage in the improper promotion or sales of Purdue's products;" (2) monitor sales representatives' interactions with prescribers in specified ways; and (3) engage an Independent Review Organization ("**IRO**") to assess and evaluate Purdue systems, processes, policies, and procedures relating to sales, marketing, and promotion of OxyContin.[84] Purdue undertook extensive reporting obligations to OIG.[85]

62. As part of the 2007 Federal Settlement, the federal government released the Sackler family members who had a role at Purdue from all civil and criminal liability arising out of Purdue's sale and marketing of OxyContin prior to May 10, 2007. In the civil settlement, the federal government released "Purdue and its current and former directors, officers, employees, affiliates, owners, predecessors, successors and assigns" from any civil or administrative claim under any statute creating causes of action for civil damages or penalties, or common law, or equitable or disgorgement theories for conduct related to the marketing of OxyContin.[86]

63. In the 2007 Guilty Plea, the federal government released claims for violations of law prior to May 10, 2007, pertaining to OxyContin "against the following, or any property owned by any of the following: Purdue, its current and former directors, officers, employees, ... owners (including trustees and trust beneficiaries of such owners) …; any of Purdue's related and associated entities … and such related and associated entities' current and former directors,

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84 *Id.* at 6-16 and Appendix B, § I.

85 *Id.* at 25-31.

86 *See* Information, Attachment D at ¶2, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 5-4 ("**2007 Civil Settlement Agreement**").

officers, employees, owners (including trustees and trust beneficiaries of such owners), ... and trusts for the benefit of the families of the current and former directors of Purdue, including the trustees and trust beneficiaries of such trusts."[87]

64. In mid-2007, Purdue also entered into Consent Judgments ("**2007 State Consent Judgments**") with 26 states and the District of Columbia ("**Consent Judgment States**"), settling claims related to "Purdue's promotional and marketing practices regarding OxyContin."[88] Purdue paid $19.5 million[89] and agreed to follow a detailed set of "compliance provisions" requiring that Purdue:

- Not "market or promote OxyContin in a manner that is, directly or indirectly, inconsistent with the … Package Insert [FDA-approved label]"[90] or "make misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert."[91]

- Establish, implement and follow, for 10 years, an OxyContin Abuse and Diversion Detection Program designed to identify potential abuse and diversion of OxyContin, requiring Purdue employees and sales representatives to report to the Office of the General Counsel observations such as, *inter alia*, "a) an apparent pattern of an excessive number of patients for the practice type …; b) an atypical pattern of prescribing techniques or locations …; c) information from a highly credible source or several sources (e.g., pharmacists, law enforcement, other health

87 *See* Plea Agreement at ¶11, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007), ECF No. 6 ("**2007 Plea Agreement**").

88 The Consent Judgment States were Arizona, Arkansas, California, Connecticut, the District of Columbia, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin. *See* Consent Judgment at 1 & ¶1.M, *In re Purdue Pharma L.P.*, No. 07-C-00740 (Ky. Cir. Ct., Franklin Cty. May 8, 2007) ("**Ky. Consent Judgment**").

89 *See* Ky. Consent Judgment at ¶25.

90 *Id.* at ¶3.

91 *Id*. at ¶5.

care workers) that a Health Care Professional or their patients are abusing or diverting medications."[92]

- "[C]onduct an internal inquiry" of such reports and "take such further steps as may be appropriate based on the facts and circumstances."[93]

- Not provide incentive bonus credits for sales "earned for a Health Care Professional who has been identified through the OxyContin Abuse and Diversion Detection Program as one upon whom sales representatives shall not call" and not compensate sales professionals "based exclusively on the volume of OxyContin sales."[94]

- Provide the states annually for three years statistics on "the number of reports, the number of investigations, and a summary of the results, including the number of 'Do Not Call' [*i.e.*, Region Zero] determinations," with the caveat that the reports "shall not include the names of any specific Health Care Professionals," and provide additional state-specific information to the Attorney Generals "upon written request."[95]

65. Each of the 27 Consent Judgment States "release[d] and forever discharge[d], to the fullest extent permitted by law, Purdue and its past and present officers, directors, shareholders, employees, ... affiliates, [and] parents … of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Attorney General could have asserted ... under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment" based on Purdue's promotional and marketing practices regarding OxyContin.[96]

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92 *Id*. at ¶13. The ADD Program, which predated the 2007 Consent Judgments, was previously known by its governing Standard Operating Procedure ("**SOP**")—SOP 1.7.1—which was instituted in November 2002. *See* 11/1/02 ADD SOP 1.7.1 (PPLP003430434).

93 Ky. Consent Judgment at ¶13.

94 *Id*. at ¶17.

95 *Id*. at ¶24. Region Zero was Purdue's list of suspect prescribers to whom it did not promote OxyContin.

96 *Id*. at ¶35.

66. In 2007, Purdue also settled with 48 states and the District of Columbia (the "**Medicaid Settlement States**")[97] all Medicaid claims based on allegations that Purdue "marketed OxyContin as less subject to abuse, illicit use and diversion and as less addictive and less likely to cause tolerance and withdrawal than other pain medications."[98]

67. Each state executed a settlement agreement that resolved claims for damage to the settling state's Medicaid program. In its settlement agreement, each settling state, "on behalf of itself, its officers, agents, agencies and departments," released Purdue "and its current and former directors, officers, employees, affiliates, owners, predecessors, successors and assigns" from any "civil or administrative monetary claim that the State has or may have for any claim submitted, or caused to be submitted, to the State Medicaid Program" related to the marketing of OxyContin.[99]

68. The Medicaid Settlement states reserved, and did not release, nine separate categories of claims, including "any civil or administrative liability that the Company has or may have under any state statute, regulation, or rule not covered by the release."[100] In return, Purdue agreed to "cooperate with and furnish to the State non-privileged documents and records in its possession relevant to a pending state investigation or matter."[101]

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97 The Medicaid Settlement States included every State except Kentucky and West Virginia.

98 *See* Information, Attachment M at ¶II.D, *United States v. The Purdue Frederick Co.*, 1:07-cr-0029 (W.D. Va. May 10, 2007) (ECF No. 5-14) ("**Form of State Settlement and Release**"). These settlements were contemplated by Purdue's 2007 federal guilty plea, which provided for the payment of dedicated settlement funds to compensate each state that elected to settle its related civil claims against Purdue and annexed a model form of settlement and release for the participating states to use. *See id*. and 2007 Guilty Plea at ¶3.b(2).

99 *See* Form of State Settlement and Release at ¶III.E.2. All 49 Medicaid Settlements follow this form.

100 *Id*. at ¶III.E.3.

101 *Id*. at ¶III.E.6.

69. The Medicaid Settlement States included every State except for (1) Kentucky, which was party to the 2007 State Consent Judgments and, later, another 2015 settlement with Purdue containing broad OxyContin-related releases,[102] and (2) West Virginia, which had already settled with Purdue pursuant to a December 14, 2004 agreement releasing "all claims of whatsoever kind or nature relating to OxyContin Tablets" against Purdue and its "present, former, or future ... principals, agents, ... officers, directors, shareholders, owners, employees, attorneys, representatives, subsidiaries, divisions, affiliates, associated companies, holding companies, partnerships and joint ventures."[103]

IV. PPI'S BOARD AND PURDUE'S COMPLIANCE PROGRAMS

A. *The 2005 Compliance Charter*

70. In 2005, the PPI Board adopted the 2005 Corporate Compliance Charter. The 2005 Corporate Compliance Charter established a "formal Board mandate covering Purdue's commitment to an ethical corporate culture and a compliance program."[104]

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[102] 12/18/15 settlement between Purdue and Kentucky (PPLPUCC000701839). In this settlement, Kentucky released Purdue and Sackler family members and entities for "all conduct … relating to any Purdue Opioid … including but not limited to conduct relating to ... the purchase, use, misuse, abuse, theft, prescription, marketing, manufacture, distribution, sale, promotion … and/or ingestion of any Purdue Opioid." *Id.*

[103] 12/15/04 Settlement Agreement and Release, *State of West Virginia v. Purdue Pharma, L.P.*, No. 01-CV-137 (W. Va. Cir. Ct. McDowell Cty.) (VF 00932234).

[104] 9/20/05 Email from Bert Weinstein to Board, (PPLPC036000062443) at -443; 2005 Corporate Compliance Charter (PKY183307471) at -471 ("it was unanimously decided … that the Corporation be and it hereby is authorized and directed to approve for itself and on behalf of the Partnership and its wholly owned subsidiaries the Company Compliance Charter recognized under the Federal Sentencing Guidelines, the HHS Officer of the Inspector General and other Governmental bodies in the form attached hereto"); *id.* at -472.

71. The 2005 Corporate Compliance Charter required the Vice President of Corporate Compliance to implement a program satisfying each of the seven elements of an "Effective Compliance Program" as defined by HHS OIG and the Sentencing Guidelines,[105] including:

- Formation and function of departmental compliance programs,
- Performance of on-going risk assessments,
- Development and implementation of training and education programs responsive to risks assessed, and tailored to the function and responsibility of the Companies' employees and other agents,
- Development of mechanisms for compliance monitoring and auditing, including a toll-free Ethics and Compliance Hotline for reporting anonymously without fear of retaliation,
- Maintenance of effective lines of internal communication,
- Maintenance of compliance-related performance and disciplinary standards,
- Conducting periodic reviews and updates to policies and procedures adopted by the Companies, and
- Development of mechanisms for response to violations of law or Company standards (including the handling of internal investigations).[106]

B. ***The 2005 King & Spalding Audit***

72. In 2005, the PPI Board was informed that the law firm King & Spalding had conducted a review of Purdue's compliance program.

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105 The seven elements are: "1. Implementing written policies, procedures and standards of conduct. 2. Designating a compliance officer and compliance committee. 3. Conducting effective training and education. 4. Developing effective lines of communication. 5. Conducting internal monitoring and auditing. 6. Enforcing standards through well-publicized disciplinary guidelines. 7. Responding promptly to detected offenses and undertaking corrective action." *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).

106 2005 Corporate Compliance Charter (PKY183307471) at -473-74.

73. The PPI Board was informed that that the Compliance Department had received a "[h]ighly favorable King & Spalding audit" of Purdue's compliance program.[107]

74. The PPI Board was also told that King & Spalding gave "[v]ery high marks … to our compliance program overall, and for the strong Board and Senior Executive endorsement for a highly ethical culture and compliance program we are building here."[108]

C. *The 2007 Compliance Charter*

75. In 2007, the Board adopted the 2007 Compliance Charter "to make certain conforming changes to the Corporate Integrity Agreement."[109]

76. The 2007 Corporate Charter required the creation and maintenance of a Corporate Compliance Council to be chaired by the VP of Corporate Compliance[110] and including members from "the Office of the General Counsel, Human Resources, Corporate Quality, Field Operations, Risk Management and Health Policy, Medical Research, Regulatory Affairs, and Finance."[111]

77. The Compliance Council was formed to "support the Vice President, Corporate Compliance in fulfilling his/her responsibilities with respect to Purdue's compliance program," including with respect to the "analysis of Purdue's compliance risk areas and oversight of compliance training, audits, and monitoring."[112]

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107 11/1/05 Budget Presentation (PPLPC018000070210) at slide 39.

108 July 13, 2005Board Report (PPLPC026000024332) at -333.

109 Decisions of the PPI Board (PPLP004415256) at -283. *See id.* at -285-90.

110 *Id*. at -289.

111 *Id*.

112 *Id*.

D. *The PPI Board Received Repeated Reports Reflecting Management's Implementation of the 2007 Compliance Charter*

78. Throughout the Relevant Period, the Board received detailed compliance reports from the Compliance Department on a quarterly basis.[113]

79. The quarterly compliance reports documented the substantive compliance efforts undertaken by Purdue and apprised the Board of significant risks or compliance issues with

[113] *See* Aug. 8, 2007 Compliance Report (PPLP004399954); Oct. 31, 2007 Quarterly Compliance Report (PPLPC019000172297); Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607); 1Q 2008 Quarterly Compliance Report (PPLP004401169); 2Q 2008 Quarterly Compliance Report (PPLP004401342); 3Q 2008 Quarterly Compliance Report (PPLP004402032); 4Q 2008 Quarterly Compliance Report (PPLP004402205); 1Q 2009 Quarterly Compliance Report (PPLP004402651); 2Q 2009 Quarterly Compliance Report (PPLPC012000236639); 3Q 2009 Quarterly Compliance Report (PPLP004402982); 4Q 2009 Quarterly Compliance Report (PPLP004403707); 1Q 2010 Quarterly Compliance Report (PPLP004404102); 2Q 2010 Quarterly Compliance Report (PPLP004404551); 3Q 2010 Quarterly Compliance Report (PPLP004405460); 4Q 2010 Quarterly Compliance Report (PPLP004405709); 1Q 2011 Quarterly Compliance Report (PPLP004406032); 2Q 2011 Quarterly Compliance Report (PPLP004406466); 3Q 2011 Quarterly Compliance Report (PPLP004406790); 4Q 2011 Quarterly Compliance Report (PPLP004407554); 1Q 2012 Quarterly Compliance Report (PPLP004407950); Jul. 19, 2012 Quarterly Compliance Report (PPLPUCC9002892662); 3Q 2012 Quarterly Compliance Report (PPLP004408439); 4Q 2012 Quarterly Compliance Report (PPLP004409357); 1Q 2013 Quarterly Compliance Report (PPLP004409694); Jul. 25, 2013 Quarterly Compliance Report (PPLP004409783); 3Q 2013 Quarterly Compliance Report (PPLP004410506); 4Q 2013 Quarterly Compliance Report (PPLP004410797); 1Q 2014 Quarterly Compliance Report (PPLP004411166); 2Q 2014 Quarterly Compliance Report (PPLP004411277); 4Q 2014 Quarterly Compliance Report (PPLP004411811); 1Q 2015 Quarterly Compliance Report (PPLP004412071); 2Q 2015 Quarterly Compliance Report (PPLP004412152); 3Q 2015 Quarterly Compliance Report (PPLP004412546); 4Q 2015 Quarterly Compliance Report (PPLPC063000018836); Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544); 3Q 2016 Quarterly Compliance Report (PPLPUCC9002790025); Mar. 2017 Quarterly Compliance Report (PPLP004413913); Jun. 2017 Quarterly Compliance Report (PPLP004414244); Aug. 2017 Quarterly Compliance Report (PPLPC021000899767); 3Q 2017 Quarterly Compliance Report (PPLPC022001020792); Dec. 2017 Quarterly Compliance Report (PPLPC021000920798); Mar. 2018 Quarterly Compliance Report (PPLP004414931); Aug. 10, 2018 Quarterly Compliance Report (PPLP004415061). Regular compliance reports were also made to the Board even before mid-2007. *See, e.g.*, Jan. 31, 2005 Board Report (PPLPC013000125609) at -634; Apr. 15, 2005 Board Report (PPLPC022000070889) at -929; July 13, 2005 Board Report (PPLPC026000024332); Apr. 5, 2006 Compliance Report (PPLPC031000329746); Nov. 2006 Compliance Report (PPLPC031000329745); 1Q 2007 Compliance Report (PPLP004399705).

respect to each element of Purdue's Compliance Charter and compliance program. As contemplated by the Compliance Charter, the quarterly compliance reports served as a primary mechanism through which the Board monitored Purdue's compliance program. The Vice President of Corporate Compliance made oral presentations to the Directors at Board meetings, where the substance of the quarterly reports was discussed.[114]

80. In addition to the written and oral quarterly compliance reports, the Board received lengthy quarterly reports from management that provided updates on each department of PPLP that included department-specific compliance efforts, as well as a separate discussion of the Corporate Compliance Department.[115]

81. The Board also received minutes from Executive Committee meetings and supporting documents, which showed that the members of that Committee—Purdue leadership

[114] *See, e.g.*, Decisions of the PPI Board (PPLP004415256) at -283, -309, -351, -482, -535, -611, -771, -797, -826, -835, -845, -869.

[115] *See, e.g.*, 4Q 2011 Board Report (PPLPC012000362869) at -877, -887, -899, -905 (reporting sales force compliance objective was to "[o]perate within all established company policies, government laws and regulations and PhRMA guidelines to ensure complete compliance," "and there were "[n]o issues to report;" that "Totowa and Cranbury sites" were audited with "no observations or recommendations;" that IT was collaborating with Corporate Compliance "to manage all company related HCP spend in preparation for the Sunshine Act;" that "[t]he Fourth Annual Report under Purdue's Corporate Integrity Agreement was filed.… We received a limited number of clarifying questions … and answered them to [the OIG Monitor's] full satisfaction, with two minor follow up activities nearly completed."). *See also, e.g.*, 1Q 2010 Board Report (PPLP004317547) at -559 ("By letter dated April 1st, Purdue's OIG Monitor confirmed that upon its review of Purdue's Second Annual Report (submitted September 2009) and supplemental information provided in response to OIG's request, Purdue was in compliance with the terms of its Corporate Integrity Agreement during the second reporting period"); *id.* at -565 ("Human Resources[:] ... Assure program and management compliance with all regulatory and legal requirements"); *id.* at -549 ("Marketing & Sales[:] ... Compliance with all relevant policies, government law and regulation will be closely monitored"); *id.* at -552 ("Manufacturing & Supply Chain[:] Assure compliance with all FDA, DEA OSHA and EPA laws and regulations"); 2Q 2011 Board Report (PPLP004366913); 3Q 2012 Board Report (PPLP004366816); 1Q 2013 Board Report (PPLP004367540); 4Q 2013 Board Report (PPLPC002000181035).

across departments—were focused on, and attended to, the implementation of Purdue's compliance program.[116]

E. *The PPI Board Received Information Showing Purdue's Implementation of an Effective Compliance Program as Dictated by the Compliance Charter*

82. The Board was provided information with which to monitor Purdue's ongoing satisfaction of each of the seven elements of an "effective compliance program" under OIG standards and the Sentencing Guidelines, as dictated by the Compliance Charter.

83. Under the OIG standards, the first element of an "effective compliance program" is "Implementing written policies, procedures and standards of conduct" (the "**First Element**").[117]

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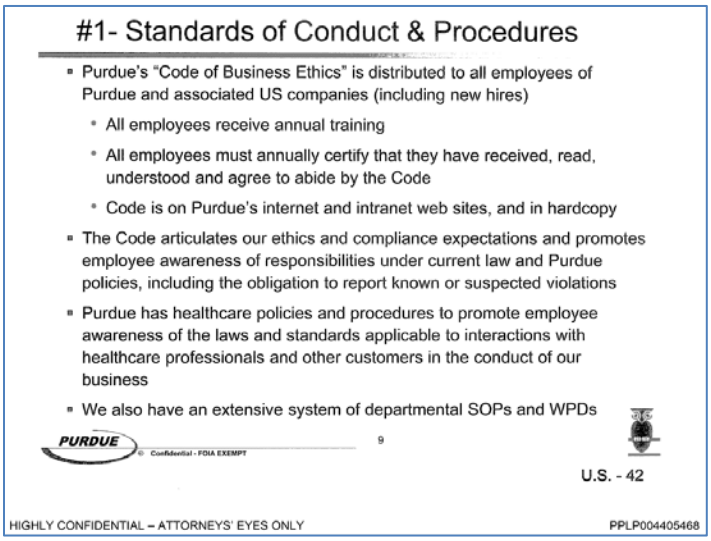
[116] *See, e.g.*, 1/24/08 Email to Board with Executive Committee Minutes (PPLPC041000006381) at -385 ("Human Resources Update" "Compensation Components[:] DL briefly reviewed the Business Success Scorecard being developed which will be used in determining the percentage of target amount to be paid for the Annual Bonus and Long-Term Results Program. The scorecard will take into consideration compliance...."); 3/8/08 Email to Board with Executive Committee Minutes (PPLPC044000015917) at -923 ("Bert Weinstein (BW) announced that a new OWL [Online Workplace Learning (training)] module to educate colleagues on Conflict of Interest will be announced shortly, and that the Totowa investigation has been resolved"); 9/30/09 Email to Board with Executive Committee Minutes (PPLPC049000029885) at -889-890 ("Bert Weinstein provided an update on the Massachusetts and Vermont restrictions on meals, which apply to all employees who are providing a meal to doctors...."); 11/24/10 email to Board with Executive Committee Minutes (PPLPC012000299851) at -866 (Power Point presentation on new OIG guidance issued Oct. 20, 2010); 8/3/11 Email to Board with Executive Committee Minutes with Attachment (PPLPC012000337158) at -162, -164 slide 7 (minutes report on 10-year plan, with related Power Point presentation emphasizing objectives to "[e]nsure that we achieve all of the above [goals] with an ongoing focus and commitment to compliance and quality"); 7/26/12 Email to Board with Executive Committee Minutes with Attachment (PPLPC057000011447) at -456-68 (Power Point presentation on Purdue's "Post-CIA Compliance Program" reporting "***Post-CIA there will be little change in Purdue's compliance program***" (italics and bold in original) and comparing ongoing compliance program vs. CIA requirements in some detail).

[117] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).

84. The Board was informed that Purdue implemented and maintained an "extensive system" of "policies and procedures" to promote employee awareness of the laws and standards applicable to interactions with healthcare professionals. *See, e.g.*, 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -468,[118] which demonstrates compliance with the First Element:



85. Many other Board reports address the same subject.[119]

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118 *See also* Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917, -919 (describing Purdue's satisfaction of all seven elements of an effective compliance program, including "Standards & Procedures" and enhancements); Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -936 (describing Purdue's satisfaction of all seven elements of an effective compliance program; also providing "sample" of "Standards & Procedures" compliance activities).

119 *See, e.g.*, Aug. 6, 2007 Compliance Report (PPLP004399954) at -963-64 (identifying "Standards (e.g., Codes, Policies/SOPs/WPDs)[:] Procedures for Code of Business Ethics[,] Distribution of Policies and Procedures per job functions[,] Selling and Marketing under FHCP requirements[,] Product Materials under FDA requirements[,] Compensation for RCPs who sell and promote[,] Off-Label information request referrals by reps[,] Info provided by Medical Services and Liaisons[,] Material and Product info provided by reps[,] Contractual arrangements (fee-for-service) with HCPs[,] Funding of activities and grants[,] Development and Production of 'Materials[,]' Discontinuation of Promotional 'Materials[,]' [and] Employee Discipline"); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917, -919 (describing Purdue's satisfaction of all seven elements of an effective compliance program, including "Standards & Procedures" and enhancements); Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -

86. Purdue's healthcare policies, procedures and compliance standards included SOPs that strictly delineated how Purdue was allowed to market OxyContin.

87. For example, Purdue's procedures required the Medical Services, Regulatory Affairs, and Legal Departments to review and approve all promotional literature before it could be used.[120] Purdue's guidelines also required that "[a]ll product claims made verbally by" Purdue sales representatives must "be consistent with the product labeling and Company approved Materials," and expressly "prohibit[ed] the use of unapproved Materials to promote Purdue products at any time."[121] They prohibited sales representatives from "draft[ing] and/or send[ing] correspondence to any Health Care Practitioner (HCP) that ha[d] not previously gone through the internal Material Review Process and received written approval for distribution," except in extremely limited circumstances unrelated to the promotion of Purdue products.[122]

88. In addition, the compliance reports informed the Board that Purdue's "compliance program [was] regularly updated."[123]

89. For example, the Board monitored updates to Purdue's policies that (i) incorporated changes to regulatory guidance in the "Sentencing Guidelines, OIG's Compliance Guidelines, and CIAs;"[124] (ii) "[f]ormalize[d] the exact criteria consultants must

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936 (describing Purdue's satisfaction of all seven elements of an effective compliance program; also providing "sample" of "Standards & Procedures" compliance activities).

120 *See* Purdue SOP Num. GC-SOP-0020, Material Review Process (POK003707782); *see also* Purdue SOP Num. REG-SOP-0060, Material Approval Process (PWA000000769).

121 11/28/07 Compliance Officer Certification (PPLP004432090) at -091.

122 *Id.* at -092.

123 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -163. *See also* Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917 (reporting on "routine updates" to "Standards & Procedures" and the "[d]evelopment of new policies & procedures").

124 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -163.

meet to be eligible for each type of HCP consultancy;"[125] and (iii) addressed "[p]lanned updates anticipated to Code of Business Ethics and Healthcare Law Compliance (HCLC) Policies."[126]

90. Under the OIG standards, the second element of an "effective compliance program" is "Designating a compliance officer and compliance committee" (the "**Second Element**").[127]

91. The Board knew that a compliance officer was in place. Bert Weinstein, Vice President of Corporate Compliance, had been reporting to them for years, and he continued in that role during the Relevant Period.[128]

92. The Board was also informed that the Compliance Council required under the CIA had been established and included members from key departments throughout Purdue.[129] The Board was advised that the Council would "assist in [the] analysis of compliance risk area, and monitor [the Company's] audits and investigations."[130]

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125 4Q 2015 Quarterly Compliance Report (PPLPC063000018836) at -839.

126 Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -919.

127 *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).

128 *See, e.g.*, 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -469.

129 *See* Aug. 6, 2007 Compliance Report (PPLP004399954) at -960 (listing members of Purdue's Compliance Council); 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -173 (reporting that the Corporate Compliance Council was established and had met, identifying its members, and advising that in its quarterly meeting on April 22, 2008, it had "reviewed CIA status and milestones, ongoing investigations, audit planning, audits and monitoring programs, hotline and other matters").

130 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -173.

93. The Board was also aware that additional compliance committees were empaneled,[131] and the quarterly compliance reports provided the Board with information to monitor these additional compliance committees and their functions.[132]

94. The third element of an "effective compliance program," is "Conducting effective training and education" (the "**Third Element**").[133]

95. The quarterly compliance reports provided the requisite data and information for the Board to confirm that Purdue was training all new Company employees, and kept all employees up to date, on its policies as well as relevant laws, regulations, and the CIA:

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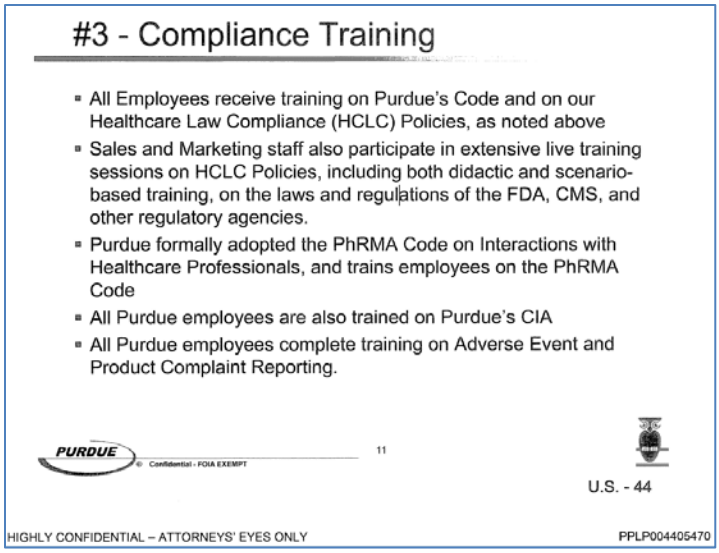
131 Purdue's compliance structure included the Corporate Compliance Council, the Sales and Marketing Compliance Committee, the Vice President's Compliance Council, the R&D Compliance, the Administrative Area Compliance Committee, the Grant Review Committees, the Reportable Events Committee, the Discipline Committee, the Quality Steering & Technical Operations Committee, the Executive Committee and the Board. *See* 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -497.

132 *See, e.g.*, Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -545 ("Ethics & Compliance, in consultation with the Law Department, is assuming ownership of several monitoring and investigation activities . . . . Ethics & Compliance is in the process of recasting the role of the Corporate Compliance Council to expand its scope to include enterprise-wide risk assessment on an ongoing basis."); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -919 (update on "Compliance Officer & Committees" reports: "Expansion for key roles – Suspicious Order Monitoring (SOM), Abuse and Diversion Detection (ADD); compliance champions;" and "Establishment of Enhanced Risk & Compliance Committee"); Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -936 ("Updated membership of Commercial Ethics & Compliance Committee;" "Convened Medical Affairs Ethics & Compliance Committee;" "Anticipating first meeting of Enterprise Compliance & Risk Management Council").

133 *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).



3Q 2010 Quarterly Compliance Report (PPLP004405460) at -470.[134]

96. The Board was advised that Purdue provided additional live training to its employees throughout the year and offered on-demand training programs through its Online Workplace Learning platform,[135] and the Compliance Department undertook ongoing "[e]fforts to continually assess educational gaps and provide targeted training."[136]

97. The VP of Corporate Compliance, Bert Weinstein, also assured the Board, and documented in compliance reports, that the "Purdue organization is well trained"[137] and that

134 *See also, e.g.*, Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -547 ("In Q1, Ethics & Compliance … partnered with Sales Training to create supplemental training (Phase II) that was provided live to all Territory Business Managers hired in 2015-2016."); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917 ("Innovative new live sales training introduced;" "27 OWL modules in 2016 – 100% completion rate").

135 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -470-71.

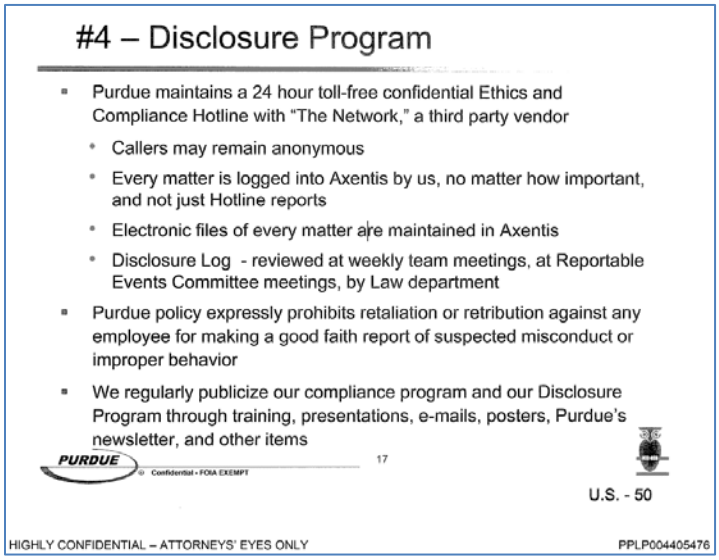
136 Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -547. *See also* 4Q 2015 Quarterly Compliance Report (PPLPC063000018836) at -839 ("Provide enhanced training of Commercial management").

137 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -163.

Purdue employees "understand the importance of compliance, and have very good understanding and skills in handling difficult compliance scenarios."[138]

98. The fourth element of an "effective compliance program" is "Developing effective lines of communication" (the "**Fourth Element**").[139]

99. The Board knew that Purdue had established "lines of communication" because, among other things, (1) the Compliance Department made quarterly compliance reports to the Board, and (2) Purdue established a "Disclosure Program," including a 24 hour toll-free confidential Ethics and Compliance Hotline, to facilitate confidential reporting of compliance concerns and continued to develop new "lines of communication" to ensure compliance.[140] *See, e.g.*, 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -476.



138 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -716; *id*. at -715 (describing training presentation "Why should compliance matter to you" and compliance "[s]cenario-based Workshops" given at Purdue's National Sales Meeting).

139 *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).

140 Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -936 ("Created robust communication plan for 2018").

100. The Board thus knew that Purdue had an Ethics and Compliance hotline that provided employees a confidential mechanism to report an ethics or compliance concern or suspected misconduct, or to obtain information and advice regarding the application of Company policies or laws.[141]

101. Purdue's compliance reports consistently updated the Board as to the number and composition of hotline calls received and demonstrated to the Board that management dealt with each of them promptly.[142] The Board also knew that Purdue maintained an "Open Door Policy" for its hotline;[143] that most hotline inquiries were "external inquiries related to medical questions;"[144] that Purdue's hotline received "[l]ower than benchmark percentage anonymous calls;"[145] and that Purdue's compliance team continued to develop new "[l]ines of [c]ommunication" to ensure compliance.[146]

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141 *See also, e.g.*, Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -959 (reporting that the "Disclosure Program/Hotline" was already in place as of "Day 0" of the CIA).

142 *See, e.g.*, 1Q 2007 Quarterly Compliance Report (PPLP004399705) at -712-15 (data on hotline calls received: number, subject matter, response time to close inquiry); 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -181-87 (same; dispositions); 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -995-99 (same); 2Q 2010 Quarterly Compliance Report (PPLP004404551) at -5 63-67 (same); 3Q 2011 Quarterly Compliance Report (PPLP004406790) at -802-05 (same); 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slides 17-19 (same).

143 Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917.

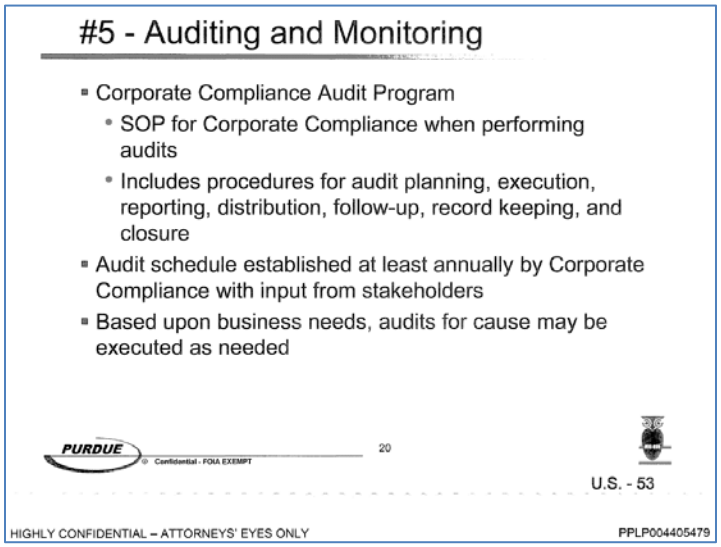
144 June 2017 Quarterly Compliance Report (PPLP004414244) at -246.

145 *Id. See also* Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -936 ("Hotline volume – remains predominantly external inquiries related to medical questions).

146 Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -936 ("Created robust communication plan for 2018").

102. The fifth element of an "effective compliance program" is "Conducting internal monitoring and auditing" (the "**Fifth Element**").[147]

103. The quarterly compliance reports told the Board that Purdue actively and effectively monitored the sales force, and conducted a variety of sales force and other audits, to detect and prevent potential violations of law, in satisfaction of the Fifth Element. As the 3Q 2010 Compliance Report summarized:



3Q 2010 Quarterly Compliance Report (PPLP004405460) at -479. Purdue management reported to the Board on compliance audits frequently,[148] including audits by third parties.[149]

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147 *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hlhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).

148 *See, e.g.*, 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -058, -081; 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -047-48; 3Q 2012 Quarterly Compliance Report (PPLP004408439) at -455; 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -798, -801, -807-08; 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -170-73; 2Q 2014 Quarterly Compliance Report (PPLP004411277) at -282-84; 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -815; 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -155; June 2017 Quarterly Compliance Report (PPLP004414244) at -246.

149 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -507, -515; 3Q 2011 Quarterly Compliance Report (PPLP004406790) at -794-97.

104. Throughout the Relevant Period, the quarterly compliance reports provided the Board with detailed information about Purdue's auditing and monitoring programs. For example, the 2Q 2011 Compliance Report contained a series of slides to answer the questions (1) "How is Purdue's Sales Force Monitored?" and (2) "How Does the Sales Monitoring 'System' Work in Practice?"[150] The slides explained that:

- District Managers monitored each member of the sales force with "Call Note Reviews and 'Call Note Annotations;'" conducted "Ride-Alongs" with each sales rep at least 8 to 12 full days each year; and issued "Field Contact Reports" that provided "detailed documentation and discussion of [each sales] representative's promotion activity" that were "[r]eviewed by Regional Directors and Management."[151]

- Other "Non-D[istrict] M[anager]" monitoring activities included additional "Ride-Alongs" concluded by Corporate Compliance, Field Trainers, the Law Department, Sales Training and others.[152]

- The District Managers' Field Contact Reports were reviewed by Corporate Compliance and each sales representative's compliance performance was "rated against 12 compliance categories," with "any not rated fully compliant result[ing] in detailed review."[153]

- The Compliance Department undertook a "Monthly Call Note Review Process" to "analyze[] all call notes for 30 key words, such as: dosing, formula, benefit, abuse, safer [and] milder."[154] Of over 125,000 call notes generated each months, approximately 25% had "hits," and "[a]ll notes with hits [were] reviewed."[155]

- The Sales force was also monitored for "Abuse, Diversion Detection Reporting," "Speaker Program monitoring," "Hotline matters," "Adverse Event Reporting," "Medical Information Requests," "Product Complaints," "Expense Reporting," "Live Training / Sales meetings," and "Direct contacts to Compliance."[156]

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150 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -482-90.

151 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -483.

152 *Id*.

153 *Id*. at -484.

154 *Id*.

155 *Id*.

156 *Id*. at -485.

- The Sales Discipline Committee held weekly meetings to track "sales investigations matters from inception to conclusion" and determine "individual and organizational remediation activities, and discipline."[157]

- Thereafter, the Compliance Council "review[ed] major matters, audits, monitoring activities," and the Sales and Marketing Compliance Committee "address[ed] key compliance risks and issues."[158]

- The outcome for investigations that identified compliance violations by the sales representatives include "Discipline"—from "coaching emails," to "warning letters," to "probation and removal;" "Retraining;" and policy updates to the tools designed to promote compliance.[159]

105. Other quarterly compliance reports showed the Board that Purdue's Compliance Department consistently reviewed, analyzed and appropriately responded to sales representative call notes, anonymous reports submitted to Purdue's hotline, and expense reports that identified potential violations of company policy or law.[160]

106. The quarterly compliance reports informed the Board that Purdue carefully monitored and audited business activities involving payments to HCPs to ensure compliance, including:

- **Speaker Programs**. The quarterly compliance reports repeatedly advised the Board that speaker programs were the subject of audits, special attention, and risk

157 *Id*. at -486.

158 *Id*.

159 *Id*. at -490.

160 *See* 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -696 (informing Board that Compliance reviewed "10% of approx. 90K call notes generated monthly" and that "[c]ompleting call notes reviews this fast has enhanced effectiveness of Sales discipline process"); 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -510 (providing overview of call note reviewed, issues found, and remediation; "% Reviewed w/Major Findings[:] 0.03%"); 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -803 ("% Reviewed w/Major Findings[:] 0.19%"); 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -816 ("Compliance matters are surfaced in many ways, including, call note monitoring, Field Contact Reports, expense and other routine monitoring activities, reports via the Hotline; and from employees and others."); Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -546 ("the most common form of discipline continues to be coaching and warning letters"); June 2017 Quarterly Compliance Report (PPLP004414244) at -246 ("Call notes to focus on new hires, new product launches").

reduction efforts.[161] The compliance reports documented the concern that speaker programs were in general a "medium"[162] to "high risk"[163] activity, but the Compliance Department had determined that the risk at Purdue was "low"[164] or "manageable"[165] because there were "appropriate safeguards in place."[166] The Board understood that the safeguards Purdue established to moderate those risks included "[l]ive monitoring" of speeches by "independent monitors" hired to "attend a significant sample of [speaker] programs nation-wide to evaluate and report" to Purdue,[167] plus "monthly monitoring by Corporate Compliance along with Sales Management training on requirements and impact."[168] The Board was apprised of other measures Purdue used to ensure that speaker programs were compliant, such as limits placed on attendees; pre-registration and pre-approval requirements for attendees; "[a]dditional training mandated for all representatives;" and "[r]efresher training prior to hosting each speaker program."[169] The

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161 *See, e.g.*, 2Q 2014 Quarterly Compliance Report (PPLP004411277) at -284 ("Compliance Audits in Progress — 2Q-2014[:] Speaker Programs[:] To assess compliance with speaker program procedures and company guidelines"); 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -815 ("Completed 13 compliance audits in 2014[.] Areas audited include … Speaker Programs.... Out of these 13 audits, there were a total of 27 findings — 0 Critical"); 1Q 2015 Quarterly Compliance Report (PPLP004412071) at -073 ("2015 Compliance Priorities … Speaker Programs"); Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -545-46 ("Compliance Risk Reduction Efforts[:] … Speaker Programs"); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -919 ("Enhanced controls and monitoring related to speaker programs"); June 2017 Quarterly Compliance Report (PPLP004414244) at -246 ("Speaker program monitoring continues").

162 4Q 2015 Quarterly Compliance Report (PPLPC063000018836) at -840; 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -171.

163 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -476; 4Q 2011 Compliance Report (PPLP004407554) at -563.

164 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -804.

165 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -476.

166 *Id.*

167 *Id. See also* 4Q 2011 Compliance Report (PPLP004407554) at -563; 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -804.

168 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -697 (reporting that, with those measures in place, the risk from non-submission of speaker program monitoring forms was "no longer an issue").

169 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -805.

Compliance Department found "no substantive concerns," and ensured that "minor issues [were] appropriately addressed."[170]

- **OIG Recommendations Concerning Speaker Programs Followed.** The Board was also informed that the OIG Monitor, Keshia Thompson, had provided Purdue with "recommendations for good compliance practices in connection with Purdue's … speaker programs," and that Corporate Compliance was "deeply involved in … establishing fair market value payments for HCPs, training of Purdue District Managers and Representatives, and monitoring arrangements … consistent with OIG's recommendations."[171]

- **Remuneration to HCPs Regulated & in Some Circumstances Barred.** The Board also understood that Purdue, under the supervision of the General Counsel's office, enforced SOPs and other policies regulating speaker programs and the use of HCPs as speakers, and strictly limited their remuneration.[172] The policies barred the payment of any fee to an HCP "for the purpose of influencing the HCP to prescribe, order, purchase or recommend any product" and required payments to HCPs be "fair market value" with no tracking for "return on investment."[173]

- **Audits of HCP Remuneration Found No Misconduct or Quid Pro Quos.** The Board was also informed that Purdue's repeated audits did not identify any concerns with remuneration paid to HCPs. For example, the Board was informed that an audit was conducted in 2013 to assess "whether there is a relationship between HCP prescribing of Purdue product, and any financial compensation received from Purdue," and it and found "no correlation."[174] Similarly, the Board was aware that, when "an audit was conducted to explore whether HCP prescribing might have been influenced by consulting payments or other value received from

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170 4Q 2011 Quarterly Compliance Report (PPLP004407554) at -563. *See also* 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -804 ("risk is low given our remedial and oversight actions").

171 4Q 2010 Board Report (PPLP004366955) at -975; *see also* 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -033, -035.

172 Purdue SOP Num. GC-SOP-0001.04, Retention of HealthCare Professionals as Consultants, Advisors and Speakers (PPLP003364388); Purdue Healthcare Law Compliance Policies (PCA000008931).

173 Purdue SOP Num. GC-SOP-0001.04, Retention of HealthCare Professionals as Consultants, Advisors and Speakers (PPLP003364388) at -389, -390. *See also* Purdue Healthcare Law Compliance Policies (PCA000008931) at -953 ("It is never appropriate to provide a gift, meal, or entertainment in order to encourage a customer [defined to include an HCP] to prescribe, purchase or order Purdue products").

174 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -808.

> Purdue," it concluded that "*[t]here was no correlation found between Purdue's financial relationships with HCPs and their prescribing of Purdue products*."[175]

107. The Board was also informed, by the quarterly compliance reports, that Purdue's Compliance Department regularly audited many other types of compliance risks, through and including, *e.g.*, "Call Note Reviews;"[176] "Fee for Service Arrangements;"[177] "Sales Force and Sales Manager Training;"[178] "training course completions;"[179] "Speaker Bureau Program Receipts and Methodology;"[180] "Systems Audit Report[s];"[181] "Topper's Audit;"[182] "Medical

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[175] 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -155 (italics in original).

[176] 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -803 ("Call note reviews are a cornerstone of sales compliance, and all notes are reviewed for key words and randomly, within 30 days of each month's-end" — reporting results of review of 25,825 call notes, findings, results and remediation); *see also, e.g.*, Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917 ("Auditing & Monitoring[:] Targeted monitoring activities - call notes (~10%), speaker programs (~10%), ride alongs (~5%)").

[177] 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -046.

[178] *Id*. at -047 (audit found "all training materials had been approved … and trainers were on topic and consistent with materials").

[179] 3Q 2012 Quarterly Compliance Report (PPLP004408439) at -455 (reporting monthly auditing and monitoring of training course completions, which "discovered that a new employee was overdue in completing four out of six CIA requirements" and reporting that this was remediated).

[180] *Id.* at -471 (audit to determine compliance to SOP requirements: "Number of Critical Findings: 0").

[181] 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -515 (Navigant Consulting retained to perform two-part audit of Sunshine Act reporting and found Purdue "'Meets Requirements, Minor Issues Noted,' with most issues addressed already").

[182] 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -807 (audit assessed "potential that the Annual Topper's Contest might incentivize the Sales Force to inappropriately promote products" and concluding: "No negative findings – no correlation").

Information Requests;"[183] "Material Review[s];"[184] "Field Contact Report Audits;"[185] "Managed Care;"[186] "Aggregate Spend – Commercial;"[187] "field coaching reports;"[188] "Ride Alongs,"[189] "CIA Training;"[190] "Vermont State law sales compliance issues;"[191] "In-Service Sign-in Sheet Audit;"[192] "FCPA / UK Bribery,"[193] and many others.[194]

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183 *Id*. (audit performed to "provide a level of assurance that inquiries received by Medical Services were not solicited and/or [to] confirm whether or not improper promotion may have occurred" and concluding: "No negative findings – no correlation").

184 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -173 (audit to "assess expired status of materials in the APRIMO system" — "No Critical Findings").

185 *Id.* (assessing "whether District Managers were accurately documenting compliance issues on Field Contact Reports" and concluding: "No Critical Findings; 3 Major Finding (timeliness of expense reporting, poor call notes, accuracy of FCR [field contact report] documentation)").

186 2Q 2014 Quarterly Compliance Report (PPLP004411277) at -283 (audit performed "[t]o provide a level of assurance that Purdue Managed Care Account Executives and Area Managers were performing activities in compliance to the Managed Care SOP," making "No Critical Findings," and reporting "Remediation is underway" for timing of submitting documentation and other lesser matters).

187 *Id*. (audit to verify "that Sales Representatives were properly documenting expenses related to Health Care Professionals" and making "No Critical Findings").

188 June 2017 Quarterly Compliance Report (PPLP004414244) at -246-47 ("Completed audit of field coaching reports," "Improved field management oversight through increased field ride alongs" and "Enhanced Field Coaching Report format").

189 *Id*. ("E&C [Ethics & Compliance] Ride alongs continuing"); Mar. 2018 Compliance Report (PPLP004414931) at -936 ("Conducted ride alongs for approximately 10% of field sales force").

190 *See, e.g.*, 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -046.

191 *Id.*

192 *Id*. at -048 (audit found that Sales representatives "conducting HCP in-services meals" had a "92% accuracy rating for data entry and reporting requirements," with improvements from previous year).

193 *Id*. at -046.

194 *See* 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -815 (listing 13 compliance audits in 2014 and reporting "a total of 27 findings — 0 Critical, 18 Major, and 9 Minor," with "All findings … satisfactorily resolved"); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -919 ("Enhanced monitoring – SOM, ADD, and Healthcare Professional (HCP) Vetting").

108. In 2013, the Board was told that Purdue found "no correlation" between sales-force incentives (specifically, the "Annual Toppers Contest," which rewarded PPLP's best salespeople in every district and the top 10% nationally) and improper promotion.[195]

109. The sixth element of an "effective compliance program" is "Enforcing standards through well-publicized disciplinary guidelines" (the "**Sixth Element**").[196]

110. The quarterly reports provided extensive information that the Board relied on to monitor the enforcement of Purdue's compliance standard and related discipline, in satisfaction of the Sixth Element.[197] The quarterly reports informed the Board that the Sales Discipline Committee held regular meetings to "[r]eview open issues, determine discipline, [and] maintain records of decisions," and the Law Department maintained a "[c]onfidential discipline database."[198] Quarterly reports to the Board made it clear that the vast majority of the compliance issues identified by the Compliance Department were not significant[199] and that

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195 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -807.

196 *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).

197 *See, e.g.*, 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -486.

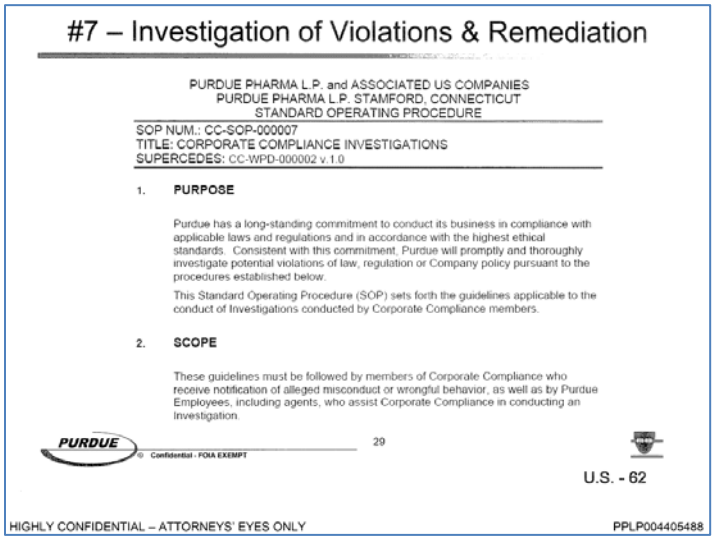
198 *See id.* at -487.

199 *See, e.g.*, 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -507 ("no significant violations or gaps"); 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -809 ("No significant compliance risks"); 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -167 ("No significant compliance issues"); 2Q 2014 Quarterly Compliance Report (PPLP004411277) at -278 ("No significant compliance issues"); 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -812 ("no significant compliance issues"); 1Q 2015 Quarterly Compliance Report (PPLP004412071) at -072 ("no significant compliance issues"); 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -153 ("no significant compliance issues"); 3Q 2015 Quarterly Compliance Report (PPLP004412546) at -547 ("no significant compliance issues"); 4Q 2015 Quarterly Compliance Report (PPLPC063000018836) at -837 ("no significant compliance issues"); Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -545 ("no *significant* compliance matters") (italics in original); June 2017 Quarterly Compliance Report

Purdue addressed all violations through discipline—ranging from warning letters, training and coaching to probation and termination.[200]

111. The seventh element of an "effective compliance program" is: "Responding promptly to detected offenses and undertaking corrective action" (the "**Seventh Element**").[201]

112. The Board was informed by the quarterly compliance reports about Purdue's compliance investigation and remediation activities. *See, e.g.*, 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -488:



#7 – Investigation of Violations & Remediation

PURDUE PHARMA L.P. and ASSOCIATED US COMPANIES
PURDUE PHARMA L.P. STAMFORD, CONNECTICUT
STANDARD OPERATING PROCEDURE

SOP NUM.: CC-SOP-000007
TITLE: CORPORATE COMPLIANCE INVESTIGATIONS
SUPERCEDES: CC-WPD-000002 v.1.0

1. **PURPOSE**

Purdue has a long-standing commitment to conduct its business in compliance with applicable laws and regulations and in accordance with the highest ethical standards. Consistent with this commitment, Purdue will promptly and thoroughly investigate potential violations of law, regulation or Company policy pursuant to the procedures established below.

This Standard Operating Procedure (SOP) sets forth the guidelines applicable to the conduct of Investigations conducted by Corporate Compliance members.

2. **SCOPE**

These guidelines must be followed by members of Corporate Compliance who receive notification of alleged misconduct or wrongful behavior, as well as by Purdue Employees, including agents, who assist Corporate Compliance in conducting an Investigation.

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(PPLP004414244) at -245 ("no significant compliance issues"); Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -932 ("No significant compliance issues").

[200] *See, e.g.*, 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -184; 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -348-49; 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -212; 3Q 2010 Board Report (PPLP004366991) at -7004; 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -490; 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -816; June 2017 Quarterly Compliance Report (PPLP004414244) at -246.

[201] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, HEALTH CARE COMPLIANCE PROGRAM TIPS, https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (last visited June 7, 2021).

113. The Board was told that Purdue had put in place policies and procedures that required the Compliance Department to "promptly and thoroughly investigate potential violations of law, regulation or Company policy."[202]

114. Through the compliance reports, the Board received a detailed overview of exemplar investigations showing how Purdue's compliance program worked in practice,[203] as well as status updates and data confirming that Purdue regularly performed investigations and remediation.[204]

115. **Proactive Board Data Request.** In 2015, the Board affirmatively requested that the Compliance Department "continue past practice of providing the Board with quarterly data" about its compliance investigations and remediation efforts.[205]

116. **Board Incentivization of Compliance.** The Board financially incentivized compliance by making employee bonus payments rise or fall depending on full satisfaction of compliance obligations. For example, a January 2011 Board Compensation Committee deck[206]

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202 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -488.

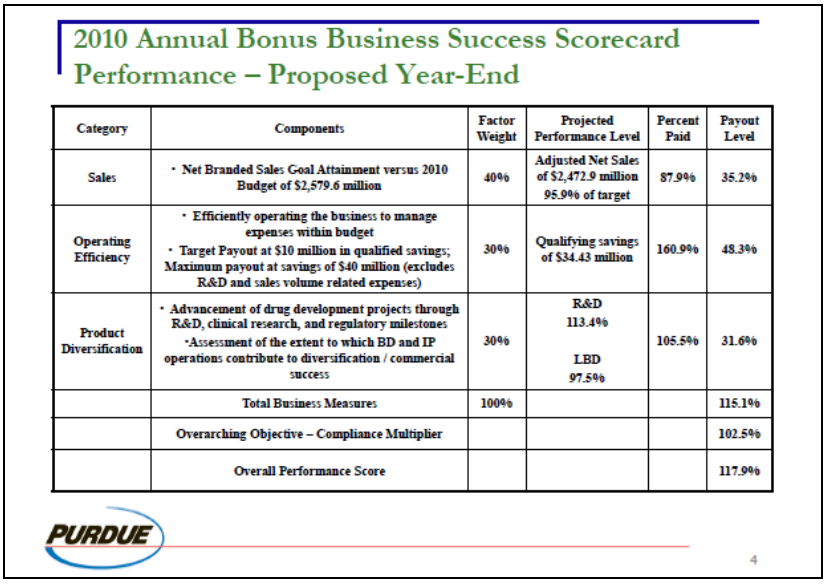
203 *See, e.g.*, 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -489-90 (telling Board: "Law and Compliance reviewed all email"; compliance "[c]onducted investigations with representatives who had more significant violations"; "Major discipline for one representative").

204 *See, e.g.*, 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -356-57 (updating Board on ongoing investigations and reporting investigation of "106 matters in 2Q08," of which "10 had compliance implications"); 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -817 (describing "Most Important Investigation of 2014"); 3Q 2015 Quarterly Compliance Report (PPLP004412546) at -551 ("Matters by Quarter"); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917 ("More than 250 inquiries and matters addressed in 2016"); March 2018 Quarterly Compliance Report (PPLP004414931) at -940 (detail on "Investigations and Inquiries: YTD 2018").

205 3Q 2015 Quarterly Compliance Report (PPLP004412546) at -550.

206 1/21/11 Board Compensation Committee deck (PPLPUCC9003754547) at slide 4.

shows the compliance multiplier of 102.5% used for the company performance portion (75%) of annual bonus determinations for executives in 2010:



2010 Annual Bonus Business Success Scorecard
Performance – Proposed Year-End

Category	Components	Factor Weight	Projected Performance Level	Percent Paid	Payout Level
Sales	• Net Branded Sales Goal Attainment versus 2010 Budget of $2,579.6 million	40%	Adjusted Net Sales of $2,472.9 million 95.9% of target	87.9%	35.2%
Operating Efficiency	• Efficiently operating the business to manage expenses within budget • Target Payout at $10 million in qualified savings; Maximum payout at savings of $40 million (excludes R&D and sales volume related expenses)	30%	Qualifying savings of $34.43 million	160.9%	48.3%
Product Diversification	• Advancement of drug development projects through R&D, clinical research, and regulatory milestones •Assessment of the extent to which BD and IP operations contribute to diversification / commercial success	30%	R&D 113.4% LBD 97.5%	105.5%	31.6%
	Total Business Measures	100%			115.1%
	Overarching Objective – Compliance Multiplier				102.5%
	Overall Performance Score				117.9%

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Separately, violations of Purdue's Abuse and Diversion Detection Program ("**ADD Program**") requirements, which are addressed below, could result in bonus ineligibility (if employment were not terminated altogether).[207]

F. *The Board Was Expressly Informed that Purdue's Compliance Program Met Or Exceeded Industry Standards*

117. In 2009, the Board asked management to "consider augmenting Purdue's compliance program to implement new features contained in the most recent CIAs."[208] In response, the VP of Corporate Compliance told the Board that Purdue was already "ahead of the curve" and provided a detailed chart showing "Recent CIA Compliance Requirements" applicable to other companies and how favorably Purdue stacked up.[209]

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207 Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -076; Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -432.

208 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -722-23.

209 *Id.*

118. The Compliance Department assured the Board again in July 2012 that Purdue's compliance program was "[s]tate of the [a]rt," and would remain so even after the CIA ended at the end of that month.[210] The report walked the Board through new elements that the most recent CIAs adopted and assured the Board that the Compliance Department would "continually review and selectively implement practices" that it concluded would be the "[f]uture … [f]ocus" of compliance efforts.[211]

119. The Board also understood that its oversight of Purdue's compliance program satisfied the OIG's evolving standards for Board oversight.[212]

120. In 2015, the Board was informed of the OIG's newly published *Practical Guidance for Health Care Governing Boards on Compliance Oversight*, a complete copy of which was provided to the Board and was the subject of a detailed presentation by the Compliance Department.[213] The presentation set out the OIG's "Expectations for Board Oversight" and how the established practices of the PPI Board satisfied those expectations.[214]

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210 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 11.

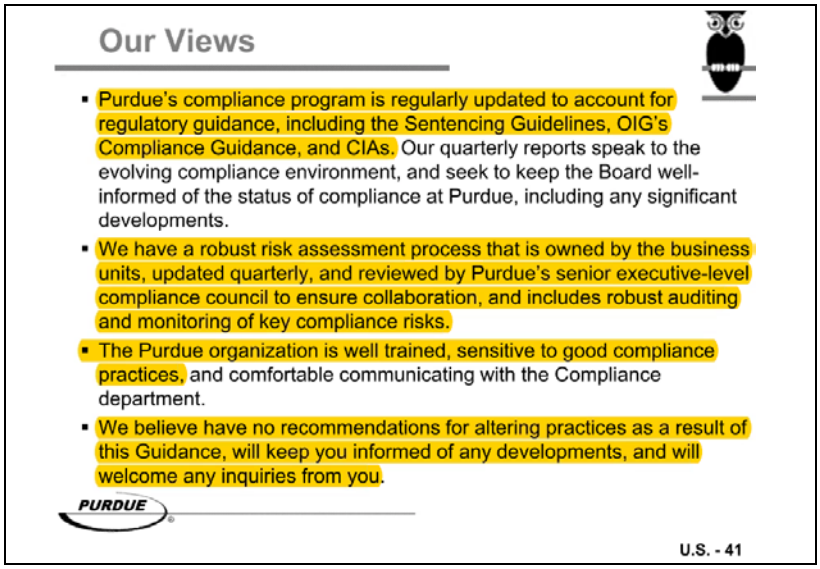
211 *Id*. at slides 12, 14-15. *See also* 4Q 2012 Quarterly Compliance Report (PPLP004409357) at -361 ("New (2012) CIA Requirements[:] … Purdue's Compliance department considers and adopts new OIG requirements to our compliance program, where applicable"); 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -800 ("We review each new CIA (as well as other external sources), and consider whether to adopt new requirements into Purdue's compliance program").

212 *See* 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -465 ("Purdue's compliance program has also been implemented pursuant to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers").

213 *See* 2Q 2015 Quarterly Compliance Report (PPLP004412152) (attaching *Practical Guidance of Health Care Governing Boards on Compliance Oversight*). *See also* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, PRACTICAL GUIDANCE FOR HEALTH CARE GOVERNING BOARDS ON COMPLIANCE OVERSIGHT, https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf (last visited June 7, 2021).

214 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -158.

The Board was advised that its oversight of the compliance program, and the compliance program itself, satisfied the OIG expectations:



G. *The OIG Monitor And The IRO Monitored And Confirmed Purdue's Compliance Efforts Between 2007 And 2012*

121. From July 31, 2007 to July 30, 2012, Purdue operated under the CIA, which imposed strict compliance and reporting requirements and placed Purdue under the monitorship of both the OIG and the IRO.[215]

122. For each one-year Reporting Period from 2007 through 2012, the Board was informed that the OIG had confirmed in writing Purdue's compliance with the CIA.[216]

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215 *See* CIA at ¶II.A; Purdue 2007 Civil Settlement Agreement ¶III.1; IRO Report on Promotional and Product Services Transactions for Reporting Period 5 (PPLPC019000720508) at -509.

216 *See* Q2 2009 Quarterly Compliance Report (PPLPC012000236639) at slide 6 ("By May 6th letter, OIG confirmed Purdue's compliance with the requirements of our CIA during the first year, based on their review of our Annual Report and other materials."); 1Q 2010 Board Report (PPLP004317547) at -549 ("By letter dated April 1st, Purdue's OIG Monitor confirmed that ... Purdue was in compliance with the terms of its Corporate Integrity Agreement during the second reporting period."); 1Q 2011 Board Report (PPLPC012000322426) at -448 ("We have received the Office of Inspector General's (OIG) January 28th letter confirming satisfactory completion of their review of Purdue's Third Annual Report: 'it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement'"); 3/8/12 OIG Letter to Purdue (PPLP004428603)

123. The Vice President of Corporate Compliance also presented quarterly compliance reports to the Board. Throughout the duration of the CIA, VP Weinstein repeatedly documented that "no significant compliance issues currently exist" and that Purdue "is in full compliance with its compliance requirements including but not limited to the Corporate Integrity Agreement."[217]

124. The Board was also advised that the OIG Monitor, Keshia Thompson, orally expressed her approval of the Purdue's compliance efforts at various points during the 5-year monitorship.

("Based on our review of this additional information and the information provided in Purdue's Fourth Annual Report, it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA) … during the fourth annual reporting period."); 1/24/13 OIG Letter to Purdue (PPLP004427723) ("Based on our review of all this information, it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA) … during the fifth annual reporting period."); 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -695 ("From Letter dated January 24th, Office of Inspector General, HHS: ...'[I]t appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement (CIA) … during the fifth annual reporting period.… [T]he Purdue CIA has now concluded.'").

[217] Decisions of the PPI Board (PPLP004415256) at -283 (May 11, 2007 Minutes of PPI Board); at -309 (Aug. 6, 2007 Minutes of PPI Board). *See also id.* at -351 (Feb. 14 Meeting of the PPI Board) ("the Partnership is in full compliance with its compliance requirements"); *id.* at -482 (Feb. 5, 2009 Minutes of PPI Board) ("the Partnership is in full compliance with its compliance requirements"); *id.* at -535 (May 8, 2009 Minutes of PPI Board) ("no significant compliance issues currently exist"); *id.* at -611 (Oct. 19, 2009 Minutes of PPI Board) ("no significant compliance issues currently exist"); *id.* at -771 (Nov. 18-19, 2010 Minutes of PPI Board) ("the Partnership is in full compliance with its compliance requirements"); *id.* at -797 (Feb. 3, 2011 Minutes of PPI Board) ("the Partnership is in full compliance with its compliance requirements"); *id.* at -826 (July 21, 2011 Minutes of PPI Board) ("the Partnership is in full compliance with its compliance requirements"); *id.* at -835 (Nov. 2, 2011 Minutes of PPI Board) ("the Partnership is in full compliance with its compliance requirements"); *id.* at -845 (Jan. 19, 2012 Minutes of PPI Board) ("the Partnership is in full compliance with its compliance requirements"); *id.* at -869 -869 (July 19, 2012 Minutes of PPI Board) ("the Partnership is in full compliance with its compliance requirements").

125. In 2010, Monitor Thompson told Purdue that its employees "consistently demonstrated compliance knowledge and awareness."[218]

126. In 2009, Monitor Thompson "was impressed to hear of the seriousness Purdue's sales force and management attached to" compliance matters.[219]

127. In addition, every year the CIA was in effect, Huron Consulting Services LLC ("**Huron**") served as IRO to "verify [Purdue's] systems, policies, processes, and procedures," and to "audit [Purdue's] data relating to promotion and dissemination of information of [*sic*] Purdue Products."[220] Huron documented its findings in eight comprehensive reports.[221]

128. Every year, the IRO examined selected Purdue areas, including those relating to sales force communications with HCPs, conducted interviews, and assessed whether Purdue properly handled potential violations.[222]

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218 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -498.

219 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -985.

220 Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -965.

221 *See* IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 1 (PPLPC057000008159); IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2 (PPLP004433812); IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 2 (PPLP004433931); IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3 (PPLP004434741); IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 3 (PPLP004434456); IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4 (PPLPC021000573227); IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4 (PPLP004432560); IRO's Report on Promotional and Product Services Transactions Engagement, Reporting Period 5 (PPLP004434983).

222 *Id.*

129. In 2009 and 2011, the IRO produced additional reports detailing what each relevant policy or procedure at Purdue entailed, how Purdue trained its employees, how it monitored employees for compliance with Purdue policies, and how it disciplined violators.[223]

130. The IRO also prepared an additional report in 2010 concerning Purdue's revision to its Healthcare Grant Review Committee SOP. To the extent the IRO made any negative findings, they were minor and Purdue appropriately responded to the IRO's recommendations.[224]

H. *The Board Understood that Purdue Further Enhanced Its Compliance Efforts After The CIA Ended*

131. On July 19, 2012, shortly before the 5-year term of the CIA ended, the Compliance Department presented a detailed report to the Board on Purdue's "Post-CIA Compliance Program," explaining in detail that the program in force under the CIA would continue essentially intact with some refinements (*e.g.*, elimination of OIG and IRO reporting requirements and incidental obligations), under the direction of the Compliance Department and the supervision of the Compliance Council.[225]

132. The 2Q 2012 Compliance Report explained:

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223 *See* IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2 (PPLP004433812) at -815 (outline of assessment of "Promotion and Product Service Systems"); IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3 (PPLP004434741) at -743-44 (outline of assessment of "Promotional and Product Service Systems" after Purdue had "revised its Healthcare Grant Review Committee … SOP"); IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4 (PPLPC021000573227) at -232 (outline of procedures for assessment of "Promotional and Product Services").

224 *See, e.g.*, 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -038 ("non-significant findings"; "All recommendations to be accomplished no later than 12/08"); Nov. 9, 2011 Quarterly Report to the Board (PPLP004366871) at -896 (the IRO report "contains a limited number of minor observations and recommendations, to which the company responded"); 3Q 2012 Quarterly Report to the Board (PPLP004366816) at -860 ("All [IRO] findings and observations are minor").

225 *See* 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 3.

- "We will continue to address compliance risks company-wide"
- "We will continue to do nearly all CIA-required compliance activities"
- "We will drop a small percentage of total workload that was OIG-centric (e.g., reporting to OIG), but expand other valuable activities."[226]

133. The 2Q 2012 Compliance Report further informed the Directors of the long list of compliance "Activities To be Continued", including quarterly reports to the Board; investigation of hotline matters and compliance issues raised in Sales Discipline; and continued escalation of "significant matters" that had been "Reportable Events" under the CIA to "Law and Compliance" and to the Corporate Compliance Council for review and redress.[227]

134. The 2Q 2012 Compliance Report assured the Board that Purdue would "continually review and selectively implement practices that" the Compliance Department believed would "add compliance value" for the Company.[228]

I. *Skadden's Compliance Role*

135. One of the assurances that the 2Q 2012 Compliance Report provided to the Board that, in anticipation of the IRO monitorship concluding, Purdue had retained health law expert John Bentivoglio of Skadden.[229] The Board was informed that Mr. Bentivoglio and Skadden—which had provided advice to PPLP on compliance matters as early as 2010[230]—would "[p]rovide ongoing reviews of Compliance Program effectiveness and improvements," "[m]eet

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226 *Id*. (emphasis added).

227 *Id*. at slide 5. *See also id.* at slides 6-8. "Reportable Events" encompass "anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or any FDA requirements relating to the labeling or promotion of products." CIA at ¶III(H).

228 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 12.

229 *See id.* at slide 7.

230 *See* Nov. 5, 2019 Decl. of Patrick Fitzgerald, Esq. at ¶4 (ECF No. 438-2).

with [the] Corporate Compliance Council and other select Committees as an outside resource," and "[c]onsult with [the] Compliance Department."[231]

136. In 2016, Purdue updated its retention of Skadden to assist it "with periodic proactive legal and compliance reviews.[232]

137. In 2016, the Board was informed that Skadden conducted a review of Purdue's Commercial Compliance Program (field promotional activities) and gave it a positive review.[233] The Board was told that Skadden concluded that "compliance controls are consistent with industry practice and requirements established in recent Corporate Integrity Agreements between pharmaceutical manufacturers and OIG."[234] The Board was told that management proactively implemented Skadden's suggestions.[235]

J. *From 2007-2018, Management Certified and Documented Purdue's Compliance with Law in Quarterly Reports to the Board*

138. From the date of the 2007 Federal Settlement through the end of the last Side B Director's tenure as a director in 2018, Purdue management certified to the Board each quarter that Purdue was operating in compliance with law. Management substantiated its certifications in thorough compliance reports from the Compliance Department.[236]

139. Management documented Purdue's compliance efforts in detail, identifying issues that had arisen and steps taken by the Compliance Department to resolve them.

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231 July 19, 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 7.

232 Nov. 5, 2019 Decl. of Patrick Fitzgerald, Esq. at p. 21 (ECF No. 438-2).

233 4Q 2015 Quarterly Compliance Report (PPLPC063000018836) at -837-38.

234 3Q 2016 Quarterly Compliance Report (PPLPUCC9002790025) at slide 3 (notes).

235 Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -545 ("We also anticipate additional proactive program enhancements to occur in late 2016/ early 2017.").

236 *See* n.218, *supra*.

140. Every report concluded with management's reasoned determination that Purdue had satisfied all of its compliance obligations during the relevant period. Representative excerpts follow in the next eleven paragraphs.

141. In 2007, management told the Board that: "Purdue is in full compliance with AG Agreement" — "Purdue is in full compliance with CIA" — "Full compliance with State Law Requirements."[237]

142. In 2008, management told the Board that: "First Annual Report to OIG submitted ... certifies to all CIA requirements" — "Purdue is also in full compliance with its AG Agreements" — "State Law Reporting Update[:] ... No compliance issues identified."[238]

143. In 2009, management told the Board that: "Review of call notes and other monitoring has uncovered[:] No Improper Promotion[;] No Inappropriate discussion of abuse, diversion, tolerance, withdrawal[;] No violations of Law" — "State Law Reporting Update[:] ... No compliance issues identified."[239]

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[237] Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -955*; see also* 3Q 2007 Board Report (PPLPC012000157402) at -461 ("We investigated a total of 39 ... matters during the third quarter of 2007. None of these matters were of significant concern"); 4Q 2007 Board Report (PPLP004367604) at -629 ("We investigated a total of 83 ... matters during the fourth quarter of 2007. None of these matters were of significant concern").

[238] 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -036, -044. *See also, e.g.*, Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slide 3 ("Purdue in compliance with AG Agreements"); 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -171 ("Purdue in compliance with AG Agreements"); 1Q 2008 Board Report (PPLP004367134) at -157 ("We investigated a total of 83 ... matters during the first quarter of 2008. None of these matters were of significant concern"); 2Q 2008 Board Report (PPLP004367297) at -324 ("We investigated a total of 93 ... matters during the second quarter of 2008. None of these matters were of significant concern"); 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -036 ("Purdue is ... in full compliance with its AG Agreements"); 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -220 ("No compliance issues identified").

[239] 1Q 2009 Quarterly Compliance Report (PPLP004402651) at -654, -665. *See also* 2Q 2009 Quarterly Compliance Report (PPLPC012000236639) at slide 3 ("All requirements were fully met for CIA year 2, ended 7/30/09"); 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -984 ("all requirements fully met for CIA year 2, ended 7/30/09"); *id.* at -986 ("Purdue is ... in full

144. In 2010, management told the Board that: "Year three of Purdue's five year CIA closes as of July 30, with all requirements met."[240]

145. In 2011, management told the Board that: "All requirements under the CIA have been met in Reporting Period 4, including all critical field-based CIA requirements" — "Marketing & Sales[:] ... No compliance shortcomings to report."[241]

146. In 2012, management reported to the Board that: "[T]he Company continued to maintain a state of effective compliance."[242]

147. In 2013, management informed the Board that: "There are no significant violations or gaps to report."[243]

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compliance with its AG Agreements"); 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -718 ("No significant matters outstanding").

[240] 2Q 2010 Board Report (PPLP004367018) at -034. *See also* 1Q 2010 Quarterly Compliance Report (PPLP004404102) at -104 (advising the Board that the OIG of HHS confirmed in writing that "it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement ... during the second annual reporting period"); 4Q 2010 Quarterly Compliance Report (PPLP004405709) at -711 ("CIA Year #3 closed 7/30/10, with 100% completion of all requirements").

[241] 2Q 2011 Board Report (PPLP004366913) at -915, -20, -40. *See also* 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -034, -050 (reporting on and forwarding letter from OIG of HHS confirming that "it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement" for year 3 of the CIA); 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -468 ("All requirements under the CIA have been met in Reporting Period 4, including all critical field-based CIA requirements"); 3Q 2011 Board Report (PPLP004366871) at -896 ("All requirements under Purdue's CIA have been met in Reporting Year 4").

[242] 4Q 2012 Quarterly Compliance Report (PPLP004409357) at -363. *See also* 1Q 2012 Quarterly Compliance Report (PPLP004407950) at -950 ("Corporate Integrity Agreement — no significant issues in 1Q12"); 3Q 2012 Quarterly Compliance Report (PPLP004408439) at -449 ("Through the Third Quarter, the Company continues to maintain a state of effective compliance. . . . There have been no significant compliance matters to report for the third quarter"); 4Q 2012 Quarterly Compliance Report (PPLP004409357) at -363 ("Throughout 4Q12, the Company continued to maintain a state of effective compliance").

[243] 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -507 (also reporting that: "The Company continues to have good systems and processes in place committed to the prevention and detection of violations, with continuous attention to improvement"). *See also* 1Q 2013 Board Report (PPLP004367540) at -591 ("Throughout the First Quarter, the Company continues to

148. In 2014, management told the Board that: "There have been no significant compliance issues in ... Full Year 2014."[244]

149. In 2015, management told the Board that: "There have been no significant compliance issues."[245]

150. In 2016, management told the Board that: "In 2016, there were no significant compliance issues."[246]

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maintain a state of effective compliance. . . . [T]here have been no significant compliance matters to report"); 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -695 (quoting OIG letter confirming that "it appears that Purdue was in compliance with the terms of the Corporate Integrity Agreement ... during the fifth annual reporting period"); 2Q 2013 Board Report (PPLPC012000433388) at -436 ("Throughout the Second Quarter, the Company continues to maintain a state of effective compliance. . . . [T]here have been no significant compliance matters to report"); 3Q 2013 Board Report (PPLPC002000186911) at -956 ("Throughout 3Q13, the Company continues to maintain a state of effective compliance. . . . [T]here have been no significant compliance matters to report"); 4Q 2013 Quarterly Compliance Report (PPLP004410797) at -798 ("There are no significant compliance violations to report"); 4Q 2013 Board Report (PPLPC002000181035) at -073 ("Throughout the 4th Quarter, the Company continues to maintain a state of effective compliance. . . . [T]here have been no significant compliance exposures to report. The Company continues to have a compliant culture, and good systems and processes in place to prevent violations of law, regulations, and other standards.").

[244] 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -812. *See also* 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -167 ("No significant compliance issues to date in 2014"); 2Q 2014 Quarterly Compliance Report (PPLP004411277) at -278 ("No significant compliance issues in the 2nd quarter, or to date in 2014").

[245] 1Q 2015 Quarterly Compliance Report (PPLP004412071) at -072. *See also* 2Q 2015 Quarterly Compliance Report (PPLP004412152) at -153 ("There have been no significant compliance issues in the 2nd quarter, 2015"); 3Q 2015 Quarterly Compliance Report (PPLP004412546) at -547 ("There have been no significant compliance issues in the 3rd quarter, 2015"); 4Q 2015 Quarterly Compliance Report (PPLPC063000018836) at -837 ("There have been no significant compliance issues in the 4th quarter, 2015").

[246] Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -917. *See also* Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544) at -545 ("Throughout the first half of 2016, the Company maintained compliance with applicable laws and regulations. . . . [T]here have been no significant compliance matters to report.").

151. In 2017, management told the Board that: "No significant compliance issues to report."[247]

V. PURDUE'S ANTI-DIVERSION PROGRAMS

152. The risk of abuse and diversion has been prominently displayed on the OxyContin label for decades, from its first label through present day.[248]

153. The PPI Board did not have a day-to-day role in implementing Purdue's anti-diversion activities, including the Company's ADD Program. For example, the Board was not involved in, or informed about, decisions management made as to individual prescribers and whether to continue to call on (or "detail") them (the Region Zero determinations).

154. Detailed compliance and other management reports informed the Board that Purdue was vigorously implementing and monitoring the ADD Program.[249]

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[247] Mar. 2018 Quarterly Compliance Report (PPLP004414931) at -932. *See also* June 2017 Quarterly Compliance Report (PPLP004414244) at -245 ("There are no significant compliance issues to report.").

[248] *See, e.g.*, 1995 OxyContin FDA-Approved Label (PPLPC044000064536) at -537 ("OxyContin is a mu-agonist opioid with an abuse liability similar to morphine and is a Schedule II controlled substance. Oxycodone products are common targets for both drug abusers and drug addicts.... [C]are should be taken to prevent diversion or abuse by proper handling."); July 2001 OxyContin FDA-Approved Label (PDD1501070063) at -069 ("Oxycodone, like morphine and other opioids used in analgesia, can be abused and is subject to criminal diversion."); Sept. 2018 OxyContin label § 5.1, *available at* https://www.fda.gov/media/131026/download ("Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."); 2021 OxyContin FDA-Approved Label at 1, 13, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf ("OXYCONTIN exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death;" "Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion.").

[249] *See, e.g.*, Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -955-58, -968, -970) ("Purdue is in full compliance with AG Agreement" [Purdue's shorthand for the 27 Consent Judgments it entered in 2007], including establishment of ADD Program and timely certification of same; management handling 2 reported abuse/diversion matters pursuant to SOP 1.7.1 (ADD Program) and resolving 4 compliance inquiries regarding abuse/diversion/theft); Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slides 12-13 (Compliance Dept. resolution of 5 abuse/diversion inquiries); 1Q 2008 Quarterly Compliance Report

155. Detailed compliance and other management reports informed the Board that all employees were trained on the ADD Program.[250]

(PPLP004401169) at -171 ("Abuse & Diversion Detection (ADD) training –current"), and at -186 -87 (Compliance Dept. resolution of 1 abuse/diversion incident); 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -360-61 (Compliance Dept. resolution of 2 abuse/diversion incidents); 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -049-50 (Compliance Dept. resolution of 3 abuse/diversion inquiries), and -086 (detailed graphic explaining multiple ways Purdue conducts Sales Force Monitoring, including through mandatory reporting of indications of abuse or diversion, review of Field Contact Reports, and call note keyword searches); 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -224-25 (Compliance Dept. resolution of 4 abuse/diversion inquiries); 1Q 2009 Quarterly Compliance Report (PPLP004402651) at -670-71 (Compliance Dept. resolution of 3 abuse/diversion inquiries); 2Q 2009 Quarterly Compliance Report (PPLPC012000236639) at slides 18-19 (Compliance Dept. resolution of 2 abuse/diversion inquiries); 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -720-21 (Compliance Dept. resolution of 3 abuse/diversion inquiries); 1Q 2010 Quarterly Compliance Report (PPLP004404102) at -114-15 (Compliance Dept. resolution of 5 abuse/diversion inquiries); 2Q 2010 Quarterly Compliance Report (PPLP004404551) at -566-67 (Compliance Dept. resolution of 4 abuse/diversion inquiries); 4Q 2010 Quarterly Compliance Report (PPLP004405709) at -718-19 (Compliance Dept. resolution of 3 abuse/diversion inquiries); 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -041-42 (Compliance Dept. resolution of 1 abuse/diversion inquiry); 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -480-81 (Compliance Dept. resolution of 1 abuse/diversion inquiry), and -486-90 (slide describing multiple methods of Sales Force Monitoring, followed by slides answering the question "How Does the Sales Monitoring 'System' Work in Practice?"); Attachment to Oct. 25, 2011 Exec. Comm. Notes Sent to Board (PURDUE-COR-00032186) at slides 2-4, 11-13, 18 (defining diversion, Region 0 prescribers and the ADD Program, and presenting multiple charts reflecting substantial declines in diversion and prescriptions from Region 0 prescribers following introduction of abuse-deterrent formulation); 4Q 2011 Quarterly Compliance Report (PPLP004407554) at -567-68 (Compliance Dept. resolution of 4 abuse/diversion inquiries); Jul. 19, 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 18 (Compliance Dept. resolution of 1 abuse/diversion inquiry); 4Q 2012 Quarterly Compliance Report (PPLP004409357) at -363-66 (Compliance Dept. resolution of 3 abuse/diversion inquiries); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -919-20 (describing enhanced monitoring and data mining of ADD Program); June 2017 Quarterly Compliance Report (PPLP004414244) at -248 (enhancement of ADD Program in progress).

[250] *See, e.g.*, Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slide 3 ("Purdue in compliance with AG Agreements … Abuse & Diversion Detection (ADD) training - current"); 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -171 ("Purdue in compliance with AG Agreements[.] Abuse & Diversion Detection (ADD) training - current"); 3Q 2008 Board Report (PPLP004367232) at -258 ("On September 26th, The Annual Report for First Reporting Period was submitted [to OIG], including … Certification of all compliance training"); 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -226 ("National Sales Meeting[.] Well-received compliance workshops for all field personnel: Focused on ... Abuse & Diversion

156. Detailed compliance and other management reports informed the Board that District Managers were monitoring sales representatives' detailing of prescribers and preparing written reports (Field Contact Reports or "**FCRs**") assessing the sales representatives' fulfillment of their ADD Program obligations.[251]

157. Detailed compliance and other management reports informed the Board that management was analyzing the FCRs and reporting to the Board the results of their analysis.[252]

Detection (ADD) Program reporting requirements"); 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -986 ("Purdue is also in full compliance with its AG Agreements[.] Abuse & Diversion Detection (ADD) training - current"); 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -715 ("Purdue's National Sales Meeting. . . . Scenario-based Workshops 'owned' by all the District Managers[.] Focused on … Abuse and Diversion Reporting"); 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -470-74 (extensive discussion of training on Purdue's Healthcare Law Compliance Policies, which require "Reports Pursuant to ADD Program" (*see, e.g.*, Oct. 2007 Healthcare Law Compliance Policies (PCA000008811) at -849); Jul. 19, 2012 Quarterly Compliance Report (PPLPUCC9002892662), at slide 10 ("Purdue committed to continue OxyContin Abuse and Diversion Detection Program.... Annual reminder and training to employees continues.").

[251] *See, e.g.*, 3Q 2007 Board Report (PPLPC012000157402) at -460 ("With the Law Department, we trained all employees on the terms and obligations of the AG Agreements"); July 30, 2008 Sales Force SOP (PPLP003342665) at -689; IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2 (PPLP004433812) at -834-38; 9/25/09 Second Annual Report under CIA (PPLPC063000000289); 1Q 2010 Quarterly Compliance Report (PPLP004404102) at -106; IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3 (PPLP004434741) at -750-51; 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slides 3-5; Jan. 2013 Sales Force SOP (PPLP003430093) at -131; Jan. 2016 Sales Force SOP Manual (PPLP003578668) at -717. *See also, e.g.*, 2Q 2009 Quarterly Compliance Report (PPLPC012000236639) at slide 3 (3 District Managers terminated for failing to monitor sales reps for sufficient number of days).

[252] *See, e.g.*, Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slide 6; 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -174; 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -039-40; 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -215; 1Q 2009 Quarterly Compliance Report (PPLP004402651) at -663-64; 2Q 2009 Quarterly Compliance Report (PPLPC012000236639) at slide 10; 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -991; 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -712; 1Q 2010 Quarterly Compliance Report (PPLP004404102) at -106; 2Q 2010 Quarterly Compliance Report (PPLP004404551) at -554; 3Q 2010 Quarterly Compliance Report (PPLP004405460) at 480-82; 4Q 2010 Quarterly Compliance Report (PPLP004405709) at -713; 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -034, -036; 2Q 2011 Quarterly Compliance Report

158. Detailed compliance and other management reports informed the Board that Compliance and Legal were monitoring sales call notes from sales representatives to ensure their adherence to the ADD Program.[253]

159. Detailed compliance and other management reports informed the Board that Purdue's ADD Program and other anti-diversion efforts were effective in reducing and preventing abuse and diversion.[254]

(PPLP004406466), at -469, -483, -484; 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -696-97; 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -512; 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -173. In addition, the CIA required that the IRO review and report on District Managers' monitoring of sales reps' interactions with prescribers during the CIA's second and fourth reporting years (from 8/1/08-7/31/09 and 8/1/10-7/31/11). *See* CIA §§III(D)(1)(b), III(D)(2), III(K) & Appendix B §§II(A)(7), II(B)(2). The IRO reviewed the monitoring system that Purdue put in place to assess compliance with the CIA. *See* IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2 (PPLP004433812) at -815, -833, -836, -837, -990; IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4 (PPLPC021000573227) at -245, -248, -249; IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4 (PPLP004432560) at -604. The IRO's reports were forwarded to the OIG, as required by CIA § V(B)(5), and the OIG confirmed Purdue's compliance with the CIA. *See* Second OIG Certification (PPLP004250164); Fourth OIG Certification (PPLP004428603).

253 *See* 6/15/07 ADD SOP 1.7.1 (PPLP003429997); Sept. 2015 ADD SOP 1.7.1 (PPLP004035073); Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429).

254 *See, e.g.*, Attachment to 10/25/11 Exec. Comm. Notes Sent to Board (PURDUE-COR-00032185) at slide 14 (graph entitled "ORF [OxyContin Reformulated] Drug diversion events decline by 50%"); Attachment to 10/25/11 Exec. Comm. Notes Sent to Board (PURDUE-COR-00032186) at slide 11 (graph entitled "Among Region 0 prescribers the volume decreased for all formulations" showing substantial decline following introduction of the abuse-deterrent formulation); June 12, 2012 Board Presentation (PPLPC057000011194) at Slide 9 (graph entitled "Four Drug Abuse/Diversion National Surveillance Systems" showing substantial declines in abuse and diversion following introduction of abuse-deterrent formulation); Nov. 3, 2012 Presentation to Beneficiaries (PPLP004409088) at -195 (slide entitled "Summary from Ongoing ORF [OxyContin Reformulated] Epidemiology Studies" reporting that evidence supports reduced abuse (consistent trend across studies) and reduced diversion and doctor-shopping); Mar. 21, 2013 Board Agenda (PPLPC044000041897) at -964 (graph entitled "Drug Diversion/Law Enforcement Events in RADARS® System" showing substantial decline following introduction of abuse-deterrent formulation); *id.* at -961 (graph entitled "Abuse by Individuals Assessed for Substance Abuse Treatment" showing substantial decline following introduction of abuse-deterrent formulation); *id.* at -962 (graph entitled Poison Center Data from National Poison Data System" showing substantial decline in abuse exposures following introduction of abuse-deterrent

160. Detailed compliance and other management reports informed the Board that in addition to the ADD Program, Purdue was vigorously addressing diversion by requiring field personnel to file Reports of Concern ("**ROCs**") reporting any alleged occurrences of misuse, abuse or diversion and then following up with field inquiries by management,[255] as further discussed below.

formulation); *id.* at -968 (slide entitled "Summary of Findings from Ongoing Epidemiology Studies" showing "Reduced diversion and 'doctor-shopping'" and "Reduced abuse relative to original OxyContin (consistent, durable)"); 7/25/13 Board Agenda (PPLP004409781) at -860 (slide entitled "Positive Impact of AD OxyContin" stating "Meaningful Reduction in Abuse – Especially Parenteral"); Nov. 16, 2013 Presentation to Beneficiaries (PPLPC051000193984) at -4069 (graph entitled "Change in Rates of Drug Diversion Events by Law Enforcement Agents" showing substantial decline following introduction of the abuse-deterrent formulation); *id.* at -4067 (table entitled "Reported abuse of OxyContin among abusers of any prescription opioid in the NAVIPPRO ASI-MV System (June 2009 – Dec 2012)" showing substantial decline in non-oral abuse of OxyContin following introduction of the abuse-deterrent formulation). *See also* Nov. 2011 Summary of Findings of Post-Marketing Epidemiology Study Program (PPLPC021000435532) at -585 (Figure 11 ("OxyContin diversion cases over time from 1Q2002 to 2Q2011") showing substantial decline in OxyContin diversion following introduction of abuse-deterrent formulation).

[255] *See, e.g.*, 3Q 2007 Board Report (PPLPC012000157402) at -437 ("46 field inquiries conducted [by Risk Management and Health Policy Dept.] in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); Jan. 15, 2008 Board Report (PPLP004367604) at -620 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "689 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics" and conducted "21 field inquiries ... in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); 1Q 2008 Board Report (PPLP004367134) at -149-50 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "853 ROCs regarding abuse and diversion of PPLP marketed opioid analgesics" and conducted "17 field inquiries ... in response to signals of abuse or diversion of OxyContin as identified via review of ROCs, and RADARS® System data"); July 15, 2008 Board Report (PPLP004367297) at -317 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewing "890 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics," conducting "25 field inquiries ... in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); 1Q 2010 Board Report (PPLP004317547) at -563-64 (Risk Management and Health Policy Dept. Involved in multiple "innovative programs that safeguard public health and address abuse and diversion of prescription medication"); 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -698

161. Detailed compliance and other management reports informed the Board that Purdue's anti-diversion efforts met US Government requirements.[256]

162. Detailed compliance and other management reports informed the Board that, in compliance with the 2007 Consent Judgments, in each of the years 2008, 2009 and 2010, Purdue (i) certified to the Consent Judgment States and D.C. that it had trained personnel on the ADD Program and (ii) reported the basic statistics on the ADD Program.[257]

163. Detailed compliance reports furnished to the Board quarterly from 2007 through 2018 reported—and documented—that Purdue was operating in compliance with law, the CIA (during its period of application), and the consent judgments.[258]

("'Priority Risks'" that Compliance was "[a]ddressing in 2013" include "Drug diversion issues at clinical trial sites").

256 *See, e.g.*, 1/21/10 Board Agenda (PPLPC044000023970) at -4003-05 (reporting "Losses in Transit – 0," successful "DEA 'Inspections/Audits'" and "Investigations Program" accomplishments in "Diversion (all Products) – Doctor Shopping/False Rx"); 3Q 2010 Board Report (PPLP004366991) at -998 ("DEA closed the out product diversion investigation which had been opened since early 2010"); 2012 Budget Presentation to the Board (PPLPUCC9011086649) at slide 5 ("Bottle Tracking Program: ● Agreements with 14 United States Attorneys offices and Boards of Pharmacy ● Discussions with Department of Justice on national agreement"); *id.* at slide 6 ("DEA feedback on ORF [OxyContin Reformulated] ● Statements of Barbara Boockholdt, Chief, Regulatory Section, DEA, Office of Diversion Control ▪ ORF has made a tremendous difference ▪ No longer hear about OxyContin from field offices ▪ ORF is saving lives").

257 Ky. Consent Judgment ¶24(c) and (e). *See* 5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000041921). *See also* 5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PWG004407107); 5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000064681).

258 *See, e.g.*, Oct. 31, 2007 Quarterly Compliance Report (PPLPC019000172297); Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607); 1Q 2008 Quarterly Compliance Report (PPLP004401169); 2Q 2008 Quarterly Compliance Report (PPLP004401342); 3Q 2008 Quarterly Compliance Report (PPLP004402032); 4Q 2008 Quarterly Compliance Report (PPLP004402205); 1Q 2009 Quarterly Compliance Report (PPLP004402651); 2Q 2009 Quarterly Compliance Report (PPLPC012000236639); 3Q 2009 Quarterly Compliance Report (PPLP004402982); 4Q 2009 Quarterly Compliance Report (PPLP004403707); 1Q 2010 Quarterly Compliance Report (PPLP004404102); 2Q 2010 Quarterly Compliance Report (PPLP004404551); 3Q 2010 Quarterly Compliance Report (PPLP004405460); 4Q 2010 Quarterly

164. The Board authorized the expenditure of hundreds of millions of dollars on Purdue's anti-diversion efforts, including the development of the abuse-deterrent formulation of OxyContin.[259]

165. To incentivize employees to fulfill their anti-diversion obligations, the Board incorporated accomplishment of anti-diversion obligations into employees' bonus calculations—bonuses were increased if employees fulfilled their anti-diversion obligations and were reduced if they did not.[260]

Compliance Report (PPLP004405709); 1Q 2011 Quarterly Compliance Report (PPLP004406032); 2Q 2011 Quarterly Compliance Report (PPLP004406466); 3Q 2011 Quarterly Compliance Report (PPLP004406790); 4Q 2011 Quarterly Compliance Report (PPLP004407554); 1Q 2012 Quarterly Compliance Report (PPLP004407950); Jul. 19, 2012 Quarterly Compliance Report (PPLPUCC9002892662); 3Q 2012 Quarterly Compliance Report (PPLP004408439); 4Q 2012 Quarterly Compliance Report (PPLP004409357); 1Q 2013 Quarterly Compliance Report (PPLP004409694); Jul. 25, 2013 Quarterly Compliance Report (PPLP00409781); 3Q 2013 Quarterly Compliance Report (PPLP004410506); 4Q 2013 Quarterly Compliance Report (PPLP004410797); 1Q 2014 Quarterly Compliance Report (PPLP004411166); 2Q 2014 Quarterly Compliance Report (PPLP004411277); 4Q 2014 Quarterly Compliance Report (PPLP004411811); 1Q 2015 Quarterly Compliance Report (PPLP004412071); 2Q 2015 Quarterly Compliance Report (PPLP004412152); 3Q 2015 Quarterly Compliance Report (PPLP004412546); 4Q 2015 Quarterly Compliance Report (PPLPC063000018836); Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544); 3Q 2016 Quarterly Compliance Report (PPLPUCC9002790025); Mar. 2017 Quarterly Compliance Report (PPLP004413913); June 2017 Quarterly Compliance Report (PPLP004414244); Aug. 2017 Quarterly Compliance Report (PPLPC021000899767); 3Q 2017 Quarterly Compliance Report (PPLPC022001020792); Dec. 2017 Quarterly Compliance Report (PPLPC021000920798); Mar. 2018 Quarterly Compliance Report (PPLP004414931); Aug. 10, 2018 Quarterly Compliance Report (PPLP004415061).

[259] *Testimony of Dr. Craig Landau CEO of Purdue Pharma L.P.*, PURDUE PHARMA, https://www.purduepharma.com/wp-content/uploads/2020/12/Dr.-Landau-HCOR-Written-Testimony-FINAL.pdf ("To help mitigate these risks, Purdue spent nearly a decade and hundreds of millions of dollars to reformulate OxyContin to make it more difficult to abuse by crushing, snorting, and injecting."); *Select Initiatives Addressing the Crisis*, PURDUE PHARMA, https://www.purduepharma.com/addressing-the-crisis/select-initiatives/ (stating that "Purdue has spent approximately $1 billion to develop opioids with abuse-deterrent properties" and identifying other anti-diversion efforts by Purdue).

[260] *See, e.g.*, Feb. 24, 2010 Board Proposal (PURDUE-COR-00028015) (proposal); Feb. 16, 2011 Decision Document (PPLP004417130) at -142 (proposal adopted).

A. *Purdue's ADD Program*

166. Purdue voluntarily implemented its ADD Program in 2002. The ADD Program was "designed to ensure that the company [did] not promote Purdue's products in circumstances where there [was] a concern about potential abuse or diversion related activities."[261]

167. The ADD Program relied on the information Purdue had available to it—observations made by its sales representatives, reports made by District Managers and third parties, publicly available information, and prescription data that Purdue purchased from third parties—to help Purdue identify potentially problematic prescribers, so that it could stop promoting to them.[262]

168. The ADD Program required that every ADD Covered Person (basically, everyone in contact with HCPs and pharmacists)[263] file an ADD Report promptly after s/he "learn[ed] of a

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[261] Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion (PPLPC042000024694) at slide 3.

[262] *See, e.g.*, 11/19/08 Memo from Law Department Summarizing Investigation (PWA001272123) (investigation of prescriber relied on: information from Purdue sales representative and district manager, state medical board website, call reports, and prescription history from third-party, IMS Health); 8/30/13 Memo from Law Department Summarizing Investigation (PWA001272114) (investigation of prescriber relied on: information from Purdue sales representative, state medical board website, call reports, prescription history from third-party, IMS Health, and Purdue contract and key opinion leader ("**KOL**") databases). The ADD Program charged Purdue's Law Department with the responsibility to make a determination about whether to refer an HCP to the DEA or other regulatory authorities. *See* 2/5/16 ADD Program Working Practice Document (POK003723668) at ¶5.D.2.b. *See also* Internal Inquiries: Procedures (PPLPC019000213919) at -020 ("The General Counsel's Office will take whatever steps are deemed appropriate, including but not limited to, notifying regulatory or law enforcement authorities of Purdue's concern about the conduct of a particular healthcare professional or other person."); 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶5.C.5.

[263] *See* Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -073 (defining "ADD Covered Persons" to include "all members of Purdue's field sales organization, medical science liaisons and other Purdue employees and contract or third party sales representatives who contact practicing Prescribers or Pharmacists … for the purpose of promoting a Purdue opioid product"). While the term "ADD Covered Persons" was not used in 6/15/07 ADD SOP 1.7.1, the same

circumstance or ma[de] an observation that may be indicative of potential abuse or diversion."[264] The ADD Program delineated specific objective triggers that required a report, including atypical prescribing habits; excessive numbers of patients; credible allegations of diversion, abuse or patient overdose; unauthorized prescription signing or dispensing; and investigation by authorities.[265] Information obtained during sales calls was reported through Purdue's call note system or to Drug Safety & Pharmacovigilance and was forwarded to the Law Department, and ADD Forms were available to submit to the Law Department.[266]

169. Prior to mid-2016, the Law Department was solely in charge of the ADD Program (the applicable SOP 1.7.1 was issued by the Law Department), but other departments were heavily involved. The Law Department worked in conjunction with the Compliance, Sales, Sales Operations, and Human Resources Departments to develop and maintain procedures to assist ADD Covered Persons in reporting observations or circumstances that raised concerns

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personnel had the same reporting obligations. *See* 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at -997 (definition of "Individuals With Reporting Obligations").

[264] 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at -997; Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -075; Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -431.

[265] 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at -998-99. The 2002 ADD Program contained 11 specified triggers, but Purdue revised the Program in October 2003 and again in 2007 to add additional triggers. *Compare* 11/1/02 ADD SOP 1.7.1 (PPLP003430434) at -434-35 *with* 10/6/03 ADD SOP 1.7.1 (PDD1503493410) and 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at 998-99. Purdue added another two triggers to the ADD Program in 2015, and amended the SOP to declare the purpose of the program to be "preclud[ing] promotion of Purdue's opioid products in circumstances where there is a concern about potential abuse or diversion related to a particular Prescriber, Pharmacist, his/her patients or opioid products" in connection with the Assurance of Discontinuance Purdue entered into with the State of New York. *Compare* 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at 998-99 *with* Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -073-74. *See also* AOD at ¶29(a) and (b).

[266] 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at -999; 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶5.C.

about abuse, diversion, or inappropriate prescribing of opioids, and in conducting the review and follow-up generated by those reports.[267]

170. The Law Department investigated each ADD Report, following a detailed set of procedures to determine whether to place the prescriber on the Company's No Call list—commonly referred to as Region Zero.[268] If the Law Department placed a prescriber in Region Zero, sales reps were prohibited from calling on (detailing) that prescriber and would not earn any sales incentive bonus based on prescriptions that prescriber wrote.[269]

171. The Compliance Department forwarded to the Law Department all call notes raising ADD Program concerns.[270] The Compliance Department also performed compliance risk assessments, seeking to limit exposure through a variety of actions, including policies, SOPs, training, and auditing and monitoring.[271]

172. The Sales Operations Department conducted periodic reviews of prescription and other data to identify potential abuse, diversion or inappropriate prescribing of opioids and referred identified prescribers to the Law Department for review.[272] All other departments were

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267 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶4.

268 Internal Inquiries: Procedures (PPLPC019000213919) ("In each instance in which the General Counsel's office receives notification of a sales representative's or other field personnel's concern about a healthcare professional's conduct that may indicate abuse or diversion of OxyContin or other controlled substances distributed by Purdue, the General Counsel's office will follow the procedures outlined below.").

269 *See* 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at -30000; Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -076; Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -432.

270 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶5.C (fourth bullet point).

271 *Id.*

272 *Id.*

obligated to forward to the Law Department any information they had raising concerns about a prescriber's potential abuse, diversion or inappropriate prescribing of opioids.[273]

173. In mid-2016, the Compliance Department assumed a larger role in oversight and implementation of the ADD Program.[274] It began performing the initial review, evaluation and follow-up of ADD Reports.[275] The Compliance Department forwarded to the Law Department all ADD Reports that were "not automatic 'no call' determinations"—that is, did not automatically result in the Compliance Department placing the prescriber on the Region Zero list—and the Law Department then coordinated investigations with outside counsel.[276]

174. As part of the ADD Program, Purdue monitored media sources daily for "news stories concerning adverse criminal or licensing actions taken against HCPs nationwide."[277] The Law Department, and later the Compliance Department, was responsible for reviewing "News Alerts" and, where appropriate, updating HCP profiles within the ADD system to record any news alert that triggered a further review of a given HCP.[278]

175. As noted, the Sales Operation Department had an independent obligation under the ADD Program to "conduct [a] ... periodic review of sales prescription and other data sources

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273 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -471-72.

274 *See* Aug. 25, 2016 Quarterly Compliance Quarterly Report (PPLPUCC003271544) at -545. *See also* Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -431 and 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) for the respective roles of the Law and Compliance Departments.

275 *See* Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -431.

276 *Id.*

277 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶5.C (second bullet point); 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶¶4, 5.C.2.

278 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶5.C (second bullet point); 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶6.A.

to identify potential abuse, diversion or inappropriate prescribing of opioids" and then to "refer[] prescribers who are identified to the Law Department for review," among its other ADD Program roles.[279] In addition, the Sales and Human Resources Departments worked with the Compliance and Law Departments to develop and maintain internal procedures to assist ADD Covered Persons in reporting observations or circumstances that suggested potential concerns about abuse, diversion, or inappropriate prescribing of opioids, and to conduct the review and follow up generated by those reports.[280]

176. Sales representatives were required to record in Purdue's call note system any "concerns about compliance or potential abuse issues" learned on calls with prescribers and pharmacists.[281] The Compliance Department was also charged with responsibility for identifying to the Law Department "any call notes that raise potential concerns related to compliance with the ADD Program" and summaries of "any contacts to the Ethics & Compliance Hotline that raise ADD concerns."[282]

177. The ADD Program required that Purdue's Corporate Security Department and Medical Information Department forward to the Legal Department "any information which those departments may gather that raise concerns about a prescriber's potential abuse, diversion or

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279 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶5.C (third bullet point); 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶¶4, 5.C.3, 6.C.1, 6.H.1.

280 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶4; 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶¶4, 6.H.1.

281 *See* Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at-075; Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -432.

282 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶5.C (fourth bullet point); 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶5.C.4. *See also* Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -075; Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -432.

inappropriate prescribing of opioids."[283] The IT Department also supported the ADD Program by enhancing the Phoenix customer contact system—which sales representatives used to record their call notes—"to make compliance easier, less time consuming, and more auditable."[284]

178. ADD Covered Persons were required to "receive training on the ADD Program on an annual basis;" newly hired or transferred employees were required to be trained "on the ADD Program as part of their new hire training;" and trained employees received "annual online training pursuant to an Online Workplace Learning (OWL) module disseminated by Purdue's Ethics & Compliance Department."[285]

179. The ADD Program authorized the Law Department to take a range of disciplinary actions against any employee who violated the ADD Policy, including "written warning, probation, bonus ineligibility, or termination of employment."[286]

B. *Adverse Event Reporting*

180. In addition to the ADD Program, pursuant to FDA regulations, Purdue reported to the FDA "all adverse drug experience [and] information" associated with its products, "including information derived from commercial marketing experience."[287] Purdue implemented

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283 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶5.C (fifth bullet point); 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶5.C.5.

284 2Q 2007 Board Report (PPLP004366645) at -694.

285 2/5/16 ADD Program Working Practices Document (POK003723668) at ¶5.B; 1/25/18 ADD Program Working Practices Document (PPLPC023000971903) at ¶5.B. The Compliance Department was renamed the Ethics and Compliance Department in late 2015. *See* 3Q 2015 Quarterly Ethics and Compliance Report (PPLP004412546) at -548.

286 Sept. 2015 ADD SOP 1.7.1 (PPLP004035073) at -076; Aug. 2017 ADD SOP 1.7.1 (PPLPC016000316429) at -432.

287 *See* 21 C.F.R. §314.80(b) ("each applicant having an approved application … must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source … including information derived from commercial marketing experience …").

procedures to ensure that all Purdue Employees[288] reported any "Adverse Event ... occur[ring] during the course of the drug's use in professional practice, as well as from a drug overdose, whether accidental or intentional, drug abuse, [or] [d]rug withdrawal."[289] The Adverse Event reporting obligation was not limited to Purdue's opioid medications but extended to other products, including laxatives, Betadine (surgical solution), Slow-Mag (magnesium) tablets, and all branded or generic products "with the same chemical entity as one of [Purdue's] products."[290]

181. Sales representatives and other employees were required to report Adverse Events to Purdue's Drug Safety Operations team within its Drug Safety & Pharmacovigilance Department, who, together with Purdue's Law Department, would determine the severity of the issue and appropriate follow up.[291] "Vice Presidents and respective senior management members at all company sites" were "responsible for instituting [the Adverse Events SOP] among their Employees" and ensuring employee training.[292] Purdue management regularly reported to the Board on Adverse Event training and reporting.[293]

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288 *See* MA-DSP-SOP-000001 (PPLPUCC002500202) at -203 (defining "Employee" as any "Person employed by one of more of the Associated US Companies ... or agents, consultants, licensees and/or distributors retained by the Associated US Companies").

289 2008 Training Materials (PPLP003550586) at -594. *See also* MA-DSP-SOP-000001 (PPLPUCC002500202) at ¶3 (defining "Adverse Event" as "[a]ny adverse event associated with the use of a drug (or biological product) in humans, whether or not considered drug/product related," including "in the course of the use of a drug/product in professional practice," "from drug overdose whether accidental or intentional," "from drug abuse," "from drug withdrawal," and "any failure of expected pharmacological action"); 8/22/05 Sales Training and Development re: Reporting of Adverse Events (PDD1503520499); MA-DSP-SOP-000002-Postmarketing Adverse Event Capture and Reporting (PPLP004392219) at -222.

290 2008 Training Materials (PPLP003550586) at -600-03.

291 2008 Training Materials (PPLP003550586) at -609-12, -644. *See also* MA-DSP-SOP-000001 (PPLPUCC002500202) at ¶¶1.1, 4.2.

292 MA-DSP-SOP-000001 (PPLPUCC002500202) at ¶4.2.

293 *See, e.g.*, 2Q 2007 Board Report (PPLP004366645) at -685-687, -693; 3Q 2007 Board Report (PPLPC012000157402) at -437; 4Q 2007 Board Report (PPLP004367604) at -620; 2Q

C. *Reports of Concern*

182. In addition to the ADD Program, Purdue required Field Personnel[294] to file ROCs—reports of "an alleged occurrence of misuse, abuse or diversion of a Purdue Marketed Opioid Analgesic" other than an Adverse Event[295]—with the Drug Safety & Pharmacovigilance Department.[296] The ROC SOP allocated responsibility for implementation of the policy to Vice Presidents (to institute the SOP and ensure training of all personnel); to Field Personnel (to file ROCs); to Purdue's Drug Safety & Pharmacovigilance Department (to receive and route all ROCs to the Risk Management & Health Policy Department); and to the Risk Management & Health Policy Department (to log, verify, confirm and analyze all information received as an ROC and to route to the Drug Safety & Pharmacovigilance Department for any ROCs

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2008 Board Report (PPLP004367297) at -320; 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -357; 3Q 2008 Board Report (PPLP004367232) at -249; 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -062; 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -226; 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -470-72; 2Q 2011 Board Report (PPLP004366913) at -930-931; 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -485; 2Q 2012 Board Report (PPLPC012000387069) at -089; 3Q 2012 Quarterly Compliance Report (PPLP004408439) at -454; 4Q 2014 Quarterly Compliance Report (PPLP004411811) at -816; 3Q 2015 Quarterly Compliance Report (PPLP004412546) at -550, -554; Aug. 25, 2016 Quarterly Compliance Report (PPLPUCC003271544); Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -922; June 2017 Quarterly Compliance Report (PPLP004414244) at -248.

294 "Field Personnel" included "Field Sales Representatives, District Managers, Regional Managers, National Account Managers, Account Executives, Law Enforcement Education and Liaisons, Medical Liaisons, RADARS® System Field Researchers, and any other individual with field-related activities." RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel (PPLPC039000340008) at ¶3.

295 2008 Training Materials (PPLP003550586) at -624; RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel (PPLPC039000340008) at ¶¶2.3, 3.

296 2008 Training Materials (PPLP003550586) at -624; RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel (PPLPC039000340008) at -011.

determined to constitute an Adverse Event).[297] The Risk Management & Health Policy reported to the Board that it was "Monitor[ing] Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewing ROCs and conducing field inquiries.[298]

D. *The Suspicious Order Monitoring Program and Order Monitoring System*

183. Purdue implemented the Suspicious Order Monitoring ("**SOM**") Program in 2003 in compliance with DEA regulations.[299]

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297 RM-SOP-000001-Routing of Reports of Concern regarding PPLP Marketed Opioid Analgesics by Field Personnel (PPLPC039000340008) at ¶¶3, 4.

298 *See* 2Q 2007 Board Report (PPLP004366645) at -677 ("572 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics logged for 2nd Quarter 2007 and 21 field inquiries completed" by Risk Management); 3Q 2007 Board Report (PPLPC012000157402) at -437 ("46 field inquiries conducted [by Risk Management and Health Policy Dept.] in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); 4Q 2007 Board Report (PPLP004367604) at -620 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewed "689 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics" and conducted "21 field inquiries ... in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); 1Q 2008 Board Report (PPLP004367134) at -149-50 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP's Marketed Opioid Analgesics," reviewed "853 ROCs regarding abuse and diversion of PPLP marketed opioid analgesics" and conducted "17 field inquiries ... in response to signals of abuse or diversion of OxyContin as identified via review of ROCs, and RADARS® System data"); 2Q 2008 Board Report (PPLP004367297) at -317 (Risk Management & Health Policy Dept. "Monitored Abuse and Diversion of PPLP Marketed Opioid Analgesics," reviewing "890 Reports of Concern (ROCs) regarding abuse and diversion of PPLP marketed opioid analgesics," conducting "25 field inquiries ... in response to signals of abuse or diversion of OxyContin® as identified via review of ROCs, and RADARS® System data"); 1Q 2010 Board Report (PPLP004317547) at -564 (Risk Management and Health Policy Dept. Involved in multiple "innovative programs that safeguard public health and address abuse and diversion of prescription medication"); 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -698 ("'Priority Risks'" that Compliance was "[a]ddressing in 2013" include "Drug diversion issues at clinical trial sites").

299 *See* 3/12/03 SOM SOP (PPLPC035000019501).

184. Purdue voluntarily developed the Order Monitoring System ("**OMS**") in 2008 as a supplemental DEA compliance program.[300]

185. The SOM Program required that members of Purdue's controlled substances team in Customer Service "review each order for unusual quantities or any other deviation from the customer's regular order pattern."[301] All suspicious orders had to be reported to Senior Directors at Purdue, who were tasked with "contact[ing] the customer to obtain additional information," and "provid[ing] the Associate General Counsel with all of the information gathered."[302] The SOM SOP then required Purdue's Law Department to "determine if further investigative steps [were] required and if the findings should be reported to the Field Office of the DEA."[303]

186. The OMS Program was designed to "enhance ... systems, review and vigilance in the area of suspicious order monitoring."[304] Purdue's customers were authorized distributors of Purdue's products, and each of them had an independent duty under federal law to monitor for suspicious orders made by their customers—pharmacies. The goal of the OMS Program was "to support [Purdue's] authorized distributors in their efforts in the area of Suspicious Order Monitoring."[305] OMS relied primarily on data Purdue purchased from authorized distributors to identify potentially problematic pharmacies.[306]

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300 *See* 07/21/10 Presentation to Corporate Compliance Council entitled "The Order Monitoring System" (PPLPC041000011499).

301 3/12/03 SOM SOP (PPLPC035000019501) at -501.

302 *Id.* at -502.

303 *Id.*

304 3/23/09 OMS SOP (PPLPUCC9011108993).

305 4/12/11 email from Jack Crowley to Burt Rosen, *et al.* (PPLPC053000051168) at -171.

306 3/23/09 OMS SOP (PPLPUCC9011108993).

187. Under the OMS SOP, an interdisciplinary group—from the Office of the General Counsel, CSA Compliance, National Accounts and Corporate Security—reviewed all accounts that exhibited abnormal behavior and determined whether Purdue should discuss an account with the authorized distributor or refer the account to the DEA.[307]

188. In a series of meetings in 2011 with high-ranking members of the DEA's Office of Diversion Control, Purdue officials described the SOM and OMS programs and related activities the Company had undertaken to curb diversion.[308] An email recapping an April 2011 meeting reported that Purdue discussed its OMS efforts at length and "took the opportunity to discuss potential SOM Program Improvements."[309] The email noted that DEA "seemed to be genuinely pleased with our [Purdue's] efforts."[310]

189. On October 3, 2011, Purdue referred to the DEA a list of 115 pharmacies that met two criteria: (i) total dollar volume purchases exceeding $350,000, and (ii) a reduction in order volume greater than 75% since the introduction of ADF OxyContin.[311] In addition, Purdue referred another 68 pharmacies (32 of which had previously been referred to DEA).[312]

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307 *Id.* at -995.

308 *See* 4/12/11 email from Jack Crowley describing meeting with DEA (PPLPC053000051168); 10/7/11 email from Jack Crowley to DEA following up on a meeting (PPLP004437144).

309 4/12/11 email from Jack Crowley describing meeting with DEA (PPLPC053000051168) at -171.

310 *Id*. at -170.

311 *See* 10/3/11 Email from J. Crawley to DOJ with Attachment (PPLP004437148).

312 *Id.*

190. On October 7, 2011 Purdue referred a list of 285 "slow pharmacies"—pharmacies whose OxyContin orders declined substantially after Purdue introduced ADF OxyContin—as identified using new criteria discussed with the DEA.[313]

E. *Manufacturing And Supply Chain Compliance Role*

191. In addition to the ADD, OMS, and SOM programs, the Board was informed that Manufacturing & Supply Chain was tasked with "[a]ssur[ing] compliance with all FDA, DEA, OSHA and EPA laws and regulations" in connection with the supply of Purdue pharmaceuticals.[314] Manufacturing & Supply Chain reported to the Board that it accomplished this "by auditing, monitoring key metrics and planned system upgrades/improvements (FDA, DEA, OSHA and EPA, CIA and HR policy)."[315]

F. *The Board Learned How Purdue's ADD Program And Other Anti-Diversion Measures Operated*

192. Management presentations to the Board explained the systems in place for Compliance Reporting—including reporting of "Adverse events, product complaints,

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313 *See* 10/7/11 Email from Jack Crowley to DEA referring 285 pharmacies (PPLP004437144). Purdue referred additional pharmacies to the DEA thereafter. *See* OMS Tracker, Excerpted (PPLP004474496) (*e.g.*, indicating pharmacy referrals at Rows 1186 and 1424).

314 *See, e.g.*, 4Q 2009 Board Report (PPLP004367162) at -184; 1Q 2010 Board Report (PPLP004317547) at -552; 2Q 2010 Board Report (PPLP004367018) at -024; 3Q 2010 Board Report (PPLP004366991) at -996; 4Q 2010 Board Report (PPLP004366955) at -963; 1Q 2011 Board Report (PPLPC012000322426) at -436; 2Q 2011 Board Report (PPLP004366913) at -928; 3Q 2011 Board Report (PPLP004366871) at -885; 4Q 2011 Board Report (PPLPC012000362869) at -885.

315 *See, e.g.*, 1Q 2012 Board Report (PPLPC012000374791) at -802; 2Q 2012 Board Report (PPLPC012000387069) at -087; 3Q 2012 Board Report (PPLP004366816) at -847; 4Q 2012 Board Report (PPLP004366760) at -790; 1Q 2013 Board Report (PPLP004367540) at -576; 2Q 2013 Board Report (PPLPC012000433388) at -418; 3Q 2013 Board Report (PPLPC002000186911) at -941; 4Q 2013 Board Report (PPLPC002000181035) at -059.

[i]ndications of abuse or diversion [that were] recorded in call system and automatically sent to Drug Safety & Pharmacovigilance Department."[316]

193. The Board was advised that these reporting systems, as well as reports from a variety of other sources—including the "Hotline," "Field Contact Reports," other "disclosure programs," "[m]atters found during other compliance activities," "[c]all notes," and "[p]otential compliance or regulatory matters forwarded to Corporate Compliance for review"—generated "Investigations" by the Compliance Department.[317] They also were informed that "Region 0 prescribers" were identified through the ADD Program "to ensure that the company does not promote Purdue's products in circumstances where there is a concern about potential abuse or diversion related activities."[318]

194. The Board was advised in numerous reports of management's implementation of the ADD and other anti-diversion programs.

195. The Board received regular updates on the issues that came to Purdue's attention through internal reporting sources governed by the ADD Program and the Adverse Event and ROC reporting, as well as through Purdue's call notes and hotline. The Compliance Department reported, for example, on the number of inquiries it received for investigation, how many related

316 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -086.

317 *Id*.

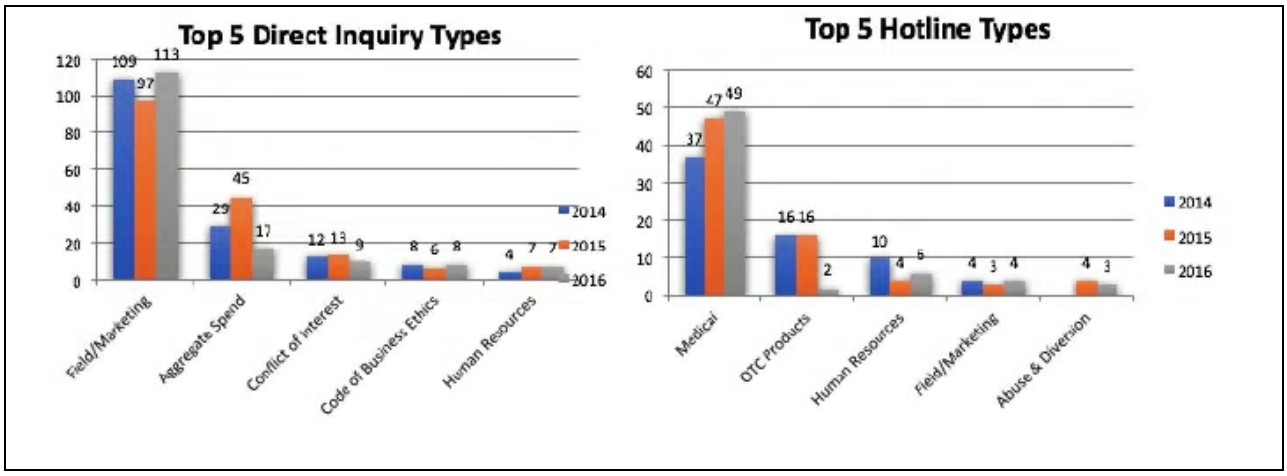
318 Attachment to Oct. 25, 2011 Exec. Comm. Notes Sent to Board (PURDUE-COR-00032186) at p. 3.

to abuse or diversion matters[319] and how long each quarter's inquiries took to close.[320] Nothing in the information presented to the Board suggested diversion problems. Very few of the

[319] *See, e.g.*, Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -968 ("101 inquiries in Q2 2007," with "2 Abuse, Diversion Matters … pursuant to RSOP 1.7.1"); Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slides 8, 12 ("86 inquiries in 4Q07," with 5 related to ADD); 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -183, -186 ("95 matters in 1Q08," with 1 related to ADD); 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -357, -360 ("106 matters in 2Q08," with 2 related to ADD); 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -046, -049 ("163 matters in 3Q08," with 3 related to ADD); 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -222, -224 ("130 matters in 4Q08," with 4 related to ADD); 1Q 2009 Quarterly Compliance Report (PPLP004402651) at -668, -670 ("125 matters in 1Q09," with 3 related to ADD); 2Q 2009 Quarterly Compliance Report (PPLPC012000236639), at slides 16, 18 ("192 matters in 2Q09," with 2 related to ADD); 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -996, -998 ("133 'matters' in 3Q09," with 1 related to ADD); 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -718, -720 ("125 'matters' in 4Q09," with 3 related to ADD); 1Q 2010 Quarterly Compliance Report (PPLP004404102) at -112, -114 ("130 'matters'" with 5 related to ADD); 2Q 2010 Quarterly Compliance Report (PPLP004404551) at -564, -566 ("134 'matters' in 2Q10," with 4 related to ADD); 4Q 2010 Quarterly Compliance Report (PPLP004405709) at -716, -718 ("200 matters in 4Q10," with 3 related to ADD); 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -039, -041 ("88 matters in 1Q2011," with 1 related to ADD); 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -478, -480 ("106 matters … in 2Q2011," with 1 related to ADD); 4Q 2011 Quarterly Compliance Report (PPLP004407554) at -564, -567 ("74 matters … in 4Q11," with 4 related to ADD); 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at 18 (57 matters in 2Q2012, with 1 related to ADD); 4Q 2012 Quarterly Compliance Report (PPLP004409357) at -366 (identifying 3 ADD issues for the "Full Year 2012").

[320] *See, e.g.*, Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -971 (most resolved within 7 days, and all within 60 days); Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at 13 (65 resolved within 7 days, 9 outstanding after 90 days); 1Q 2008 Quarterly Compliance Report (PPLP004401169) at -187 (60 resolved with 7 days, and all within 90 days); 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -361 (65 resolved with 7 days, and 2 outstanding after 90 days); 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -225 (78 resolved with 7 days, and all within 90 days); 1Q 2009 Quarterly Compliance Report (PPLP004402651) at -671 (77 resolved with 7 days, and 1 outstanding after 90 days); 2Q 2009 Quarterly Compliance Report (PPLPC012000236639) at 19 (108 resolved with 7 days, and 1 outstanding after 90 days); 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -999 (86 resolved with 7 days, and 2 outstanding after 90 days); 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -721 (88 resolved with 7 days, and all within 90 days); 1Q 2010 Quarterly Compliance Report (PPLP004404102) at -115 (70 resolved with 7 days, and all within 90 days); 4Q 2010 Quarterly Compliance Report (PPLP004405709) at -719 (152 resolved within 7 days, 2 outstanding after 90 days); 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -696 ("Monthly call note reviews now being completed on a 30 day cycle"); Mar. 2017 Quarterly

inquiries pertained to abuse or diversion, as demonstrated by two charts provided to the Board in 2017 summarizing the "Top 5 Direct Inquiry Types" and "Top 5 Hotline Types" for 2014, 2015 and 2016—and which include no ADD issues in the 5 most common direct inquiries and just 4 hotline inquiries about ADD issues in 2015 and 3 in 2016:[321]



196. Management walked the Board through the methods used to achieve—and ensure—compliance through the anti-diversion programs.

197. After the ADD Program was incorporated into the requirements of the 2007 Consent Judgements with 26 states and D.C., Purdue's management continually advised the

Compliance Report (PPLP004413913) at -922 (average days to investigate hotline calls was 11 in 2014, 7 in 2015 and 8 in 2016, and average days to investigate direct inquiries was 48 in 2014, 42 in 2015 and 49 in 2016); June 2017 Quarterly Compliance Report (PPLP004414244) at -254 (39 resolved within 7 days, 3 outstanding after 60 days).

321 Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -922.

Board over the next several years that Purdue was in full compliance with the Consent Judgments,[322] including their anti-diversion-related requirements.[323]

198. The Board was repeatedly informed that "[a]ll sales employees (and select other employees) were trained on Purdue's Abuse and Diversion Detection (ADD) Program"[324] and that annual ADD training remained "current"[325] and was "continu[ing]."[326] Board members received updates about the "extensive live training sessions," online training, field training and workshops provided to sales and marketing staff on topics including "Complete and Effective Call Notes," as required by the ADD Program.[327]

199. Management monitoring of sales representatives' call notes was a primary source of ADD Program monitoring and reporting.[328] The Board was informed that District Managers

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322 Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -955 ("Purdue is in full compliance with AG Agreement."). *See also* Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slide 3 ("Purdue in compliance with AG Agreements / Abuse & Diversion Detection (ADD) training - current"); 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -344 ("Purdue is also in full compliance with its AG Agreements"); 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -986 ("Purdue is also in full compliance with its AG Agreements"); 2/24/10 Board Proposal (PURDUE-COR-00028015) at p. 3 ("Satisfied CIA and AG requirements for all … Abuse and Diversion Detection Reports"); 1/18/12 Board Compensation Committee Presentation (PPLPC042000025057) at slide 28 ("Satisfied CIA and AG requirements for all … Abuse and Diversion Detection Reports").

323 *See* Ky. Consent Judgment at ¶¶13-14.

324 2Q 2007 Quarterly Report to the Board (PPLP004366645) at -697.

325 Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slide 3; 2Q 2008 Quarterly Compliance Report (PPLP004401342) at -344; 3Q 2009 Quarterly Compliance Report (PPLP004402982) at -986.

326 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 10.

327 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -470-74; 2Q 2007 Quarterly Report to the Board (PPLP004366645) at -697.

328 Under 6/15/2007 SOP 1.7.1, a primary procedure for a sales representative to file an ADD Report was to enter a call note into the Phoenix system. 6/15/07 ADD SOP 1.7.1 (PPLP003429997) at -999.

reviewed call notes on a weekly basis,[329] and that the Compliance Department conducted monthly word-search reviews of call notes.[330]

200. In 2011 and 2014, the Board was informed of particular management audits of the call note program.[331] Management advised that its review process included "analyz[ing] all call notes for 30 key words, such as: dosing, formula, benefit, abuse, safer, [and] milder," with over 125,000 call note hits generated each month and approximately 25% of those notes reviewed in 2011.[332]

201. The Board was informed that, by 2012, the review process had been transferred to the Compliance Department to allow "review and resolution of issues in real time"[333] and refined to include the "review of a random selection of call notes" so that "we will be looking at call notes for every representative each month."[334]

202. The Chief Compliance Officer told the Board in 2012 that "the Board's takeaway from this new process should be that Purdue is doing an even better more thorough job of monitoring field activity through these improvements."[335]

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329 3Q 2008 Quarterly Compliance Report (PPLP004402032) at -086.

330 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -207.

331 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -046 ("2011 Planned Audit List," including "Call Note Audits"); 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -472 ("Call note review, auditing"); 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -172 ("Call Note Follow-Up Audit … No Critical Findings … improvements shown from previous audit").

332 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -484.

333 3Q 2012 Quarterly Compliance Report (PPLP004408439) at -443.

334 1Q 2012 Quarterly Compliance Report (PPLP004407950) at -953.

335 *Id*. *See also* 1Q 2013 Quarterly Compliance Report (PPLP004409694) at -696 ("Reviewing 10% of approx. 90K call notes generated monthly / Faster spotting of issues"); 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -510 (11.82% of call notes reviewed).

203. Management frequently advised the Board of the results of continual Field Contact Report audits, which reflected the efficacy of Purdue's ADD Program.[336] In 2016, for example, the Board was advised that one random and one for-cause audit of Field Contact Reports had been completed to assess whether District Managers were accurately documenting compliance issues and appropriately evaluating sales reps. These audits resulted in no critical findings.[337]

204. Management reported that, at Purdue's national sales meetings, management reviewed with sales representatives ADD Report requirements,[338] gave them "Key reminders" about Abuse & Diversion Detection reporting,[339] and presented scenario-based workshops on Abuse and Diversion Reporting.[340]

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336 *See, e.g.*, 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -215-16; 1Q 2009 Quarterly Compliance Report (PPLP004402651) at -663-64; 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -712; 1Q 2010 Quarterly Compliance Report (PPLP004404102) at -106; 2Q 2010 Quarterly Compliance Report (PPLP004404551) at -554; 3Q 2010 Quarterly Compliance Report (PPLP004405460) at -492; 4Q 2010 Quarterly Compliance Report (PPLP004405709) at -713; 1Q 2011 Quarterly Compliance Report (PPLP004406032) at -036; 2Q 2011 Quarterly Compliance Report (PPLP004406466) at -469; 3Q 2013 Quarterly Compliance Report (PPLP004410506) at -512; *see also* Jan. 2013 Sales Force SOP (PPLP003430093) at -131; Jan. 2016 Sales Force SOP Manual (PPLP003578668) at -717; IRO's Report on Additional Promotional and Product Services Systems Assessment: Funding of Charitable Grants and Sponsorships, Reporting Period 3 (PPLP004434741) at -750-51.

337 1Q 2014 Quarterly Compliance Report (PPLP004411166) at -173.

338 4Q 2008 Quarterly Compliance Report (PPLP004402205) at -226.

339 Feb. 8, 2008 Quarterly Compliance Report (PPLPC019000195607) at slide 20.

340 4Q 2009 Quarterly Compliance Report (PPLP004403707) at -715.

205. Management provided regular confirmations that Purdue was meeting its ADD obligations[341] and had committed, after the end of the CIA, "to continue OxyContin Abuse and Diversion Detection Program predicated on [SOP] 1.7.1."[342]

206. The Board's Compensation Committee received consistent reports reflecting Purdue's fulfillment of its ADD Program and related efforts because they were factored into employees' compensation.[343] In 2013, this included a report that "Purdue [was] recognized by DEA, FDA, etc. for responsible actions and saving lives."[344]

207. Management advised the Board in 2010 the General Counsel's office had begun consulting with the Order Monitoring System Committee to assist with "policy development and implementation" for "new DEA requirements regarding response to "suspicious orders."[345]

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341 Oct. 31, 2007 Quarterly Compliance Report (PPLPC019000172297) at slide 11 ("All specific requirements" for the ADD program were "timely met.").

342 2Q 2012 Quarterly Compliance Report (PPLPUCC9002892662) at slide 10. *See also*, *e.g.*, Mar. 2017 Quarterly Compliance Report (PPLP004413913) at -919; June 2017 Quarterly Compliance Report (PPLP004414244) at -248.

343 *See* 2/11/09 Compliance Memo (PPLPC051000068931) at -931 ("very much heightened sensitivity to AE, ROC, product quality and ADD reporting"); 1/18/10 Scorecard Summary (PPLPC057000007180) at -192 ("the FDA and DEA inspections this year were excellent, without any adverse findings …."); 1/21/11 Presentation to Compensation Committee (PPLPC051000109841) at slide 12 ("All requirements satisfied" for "Hotline" and "Abuse and Diversion Detection Reports;" "FDA inspections and DEA audits resulted in no citations, findings or 483's"); 1/18/12 Presentation to Compensation Committee (PPLPC042000025057) at slide 28 ("Attained all objectives related to" "Hotline" and "Abuse and Diversion Detection Reports;" "Adherence to Sales SOPs," "Timely reporting of Adverse Events, Reports of Concern, Product Complaints, and Abuse and Diversion Detection Reports"); 1/21/13 Presentation to Compensation Committee (PPLPC045000016839) at -849 ("fully meeting all reporting requirements … Adherence to Sales SOPs").

344 1/18/12 President's Review of Significant Accomplishments and Disappointments in 2011 (PPLPC042000025039).

345 9/23/10 Board Agenda (PWG004349878) at -936. *See also* DEA Suspicious Orders Report System, https://www.deadiversion.usdoj.gov/sors/index.html.

G. *The 27 Consent Judgment States Required That Purdue Maintain Its ADD Program for 10 Years*

208. In the 27 State Consent Judgments that Purdue entered into in 2007, the Consent Judgment States endorsed its ADD Program by requiring that Purdue maintain the ADD Program for ten years, from 2007-2017.[346]

209. The Consent Judgments mandated that Purdue "establish, implement and follow an OxyContin abuse and diversion … program"[347]—the same program that Purdue had introduced in 2002, newly christened the Abuse and Diversion Detection Program.[348]

210. The specific indicia of potential abuse and diversion that the AGs incorporated into the Consent Judgments for the ADD Program were taken nearly verbatim from Purdue's existing ADD Program.[349] Consistent with Purdue's preexisting policies, the Consent Judgments required Purdue to investigate each ADD Report and to take "further steps as may be appropriate based on the facts and circumstances"—such as providing further education to the prescriber, stopping all marketing to the prescriber, or reporting the prescriber to the "appropriate medical, regulatory or law enforcement authorities."[350]

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346 *See* Ky. Consent Judgment at ¶13.

347. *See id*.

348. *See* 10/15/02 ADD SOP (PDD1503450011); 11/1/02 ADD SOP 1.7.1 (PPLP003430434). The ADD Program was launched on October 15, 2002, approximately 16 months after June 30, 2001, which marked the end of the period in which Purdue had engaged in the misconduct to which it pled guilty in 2007. *See* Information at ¶¶6, 20, 27, 37, 38, 43, Count One ¶2, and Agreed Statement of Facts at ¶¶20, 27, 37, 38, 43, 44, 45, *United States v. Purdue Frederick Co., Inc*., Case No. 1:07-cr-00029-JPJ (W.D. Va. May 10, 2007) (ECF No. 5) .

349 *Compare* Ky. Consent Judgment at ¶13 *with* 11/1/02 ADD SOP (PPLP003430434) and 10/6/03 ADD SOP 1.7.1 (PDD1503493410).

350 *See, e.g.,* Ky. Consent Judgment at ¶13. All 27 Consent Judgments contained identical substantive terms.

211. The Board also was informed that Purdue's updated SOP for the ADD Program in June 2007 was sent to the 27 Consent Judgment AGs, together with Purdue's certification that the ADD Program had been established and implemented, to demonstrate its compliance with the Consent Judgments' requirements.[351] None of the receiving AGs responded with any comment, criticism or objection.

212. As required, from 2008-10, the Board relied on Purdue's annual certifications to the Consent Judgment AGs confirming Purdue's compliance with the ADD Program. [352]

213. Each year, Purdue furnished to the Consent Judgment States "a report containing basic statistics on Purdue's Abuse and Diversion Detection Program including … statistics on the number of reports, the number of investigations, and a summary of the results, including the number of 'Do Not Call' determinations."[353] As mandated by the Consent Judgments, the information provided did "not include the names of any specific Health Care Professionals."[354]

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[351] *See* 6/20/07 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000033097); Aug. 6, 2007 Quarterly Compliance Report (PPLP004399954) at -956.

[352] *See* 5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000041921). *See also* 5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PWG004407107); 5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000064681). *See also* Ky. Consent Judgment at ¶24(e).

[353] Ky. Consent Judgment at ¶24(e). *See* 5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000041921). *See also* 5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PWG004407107); 5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000064681).

[354] Ky. Consent Judgment at ¶24(e). Pursuant to Consent Judgment ¶24(f), "upon written requests, the [AGs] may obtain state-specific information as described in subsection (e)."

That information was available to all Consent Judgment States on request, and it was in fact supplied to requesting AGs when they requested it.[355]

H. *The New York Attorney General's Office And The Auditor It Approved Ratified Purdue's Implementation Of The ADD Program*

214. In 2014, the New York Attorney General launched an investigation into "Purdue's Abuse and Diversion Detection ('ADD') Program (also known as the 'Region Zero' program)." This investigation concluded in August 2015 with the entry of an Assurance of Discontinuance. The AOD was entered into on a neither-admit-nor-deny basis with only $75,000 paid by Purdue in "penalties, fees and/or costs."[356]

215. In the AOD, the New York Attorney General found that Purdue's "ADD Program can be an effective tool in identifying potential abuse and illegal diversion of opioids," and determined that there were some "opportunities for improvement."[357]

216. The AOD required that Purdue maintain the ADD Program "for as long as Purdue promotes OxyContin to [prescribers] through sales representatives."[358] The AOD included modest modifications to the program, including the addition of two criteria—to the preexisting 13—that would trigger an ADD Report.[359] The AOD required that Purdue review media stories and data sources "to identify [prescribers] who should [be] reviewed for potential placement on

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355 *See, e.g.*, 5/18/09 Purdue Letter to Virginia AG (PPLPC051000075710); 10/10/13 Purdue Letter to Tennessee AG (PPLPC049000079234).

356 AOD at ¶¶8, 38.

357 *Id.* at ¶15.

358 *Id.* at ¶28.

359 *Id.* at ¶29.

the No-Call [Region Zero] List"[360] and "provide to the [New York Attorney General] the names of any [prescribers] in New York whom it has placed on the No-Call List" on a monthly basis.[361]

217. The AOD also required that Purdue hire an independent, outside auditor approved by the New York Attorney General, for a period of three years, to monitor and report on (i) Purdue's compliance with its ADD Program requirements and (ii) "the reasonableness of Purdue's decisions regarding whether to continue marketing or promoting opioid products to the [prescribers] at issue in each ADD Report"[362]—in other words, its Region Zero determinations.

218. With the New York Attorney General's approval, Purdue hired as its auditor Douglas R. Jensen, Esq., a former Chief of the Narcotics Unit in the United States Attorney's Office for the Southern District of New York. [363]

219. Beginning in 2016, the Auditor reviewed Purdue's Region Zero determinations—all "continue to call" or "resume calling" determinations Purdue's Law Department made concerning HCPs that were the subject of ADD Reports—and the Auditor produced three annual reports outlining his findings.[364] Each of those three reports confirmed that Purdue was implementing its ADD Program "reasonabl[y]," "conscientiously and in good faith," and that Purdue was in compliance with the AOD.[365]

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360 *Id.* at ¶31(d).

361 *Id.* at ¶31(c).

362 *Id.* at ¶41(b).

363 *Douglas R. Jensen*, WHITE & CASE, https://www.whitecase.com/people/douglas-jensen.

364 *See* 10/7/16 Auditor's First Report on Purdue's ADD Program (PPLP004473667); 10/20/17 Auditor's Second Report on Purdue's ADD Program (PPLP004473709); 10/19/18 Auditor's Third Report on Purdue's ADD Program (PPLP004473738).

365 10/7/16 Auditor's First Report on Purdue's ADD Program (PPLP004473667) at -668. *See* 10/20/17 Auditor's Second Report on Purdue's ADD Program (PPLP004473709) at -710 ("the Company continues to operate the ADD Program in compliance with [the AOD]"); 10/19/18

220. Over the course of three years, the Auditor identified just one determination—out of a total of 906[366]—that he thought was not reasonable. Even as to this one, the Auditor found that Purdue had acted "conscientiously" and in "good faith,"[367] and observed that, "based upon prior experience the Auditor believes it likely the Company would have reconsidered its position" in light of the Auditor's finding but, because the Company had "stopped promoting opioids to prescribers altogether on February 12, 2018, such discussions did not take place."[368]

221. In 2016, the New York Attorney General entered into an Assurance of Discontinuance with another manufacturer of oxycodone products, Endo, and it required that Endo adopt an ADD Program nearly identical to Purdue's.[369]

I. *The Board Was Aware That Other Governmental Agencies Reviewed Purdue's ADD Program And Provided No Negative Feedback*

222. The Board was informed that several governmental agencies reviewed Purdue's ADD Program, and none criticized or commented negatively on the program. [370]

Auditor's Third Report on Purdue's ADD Program (PPLP004473738) at -740 ("the Company continued to operate the ADD Program in compliance with [the AOD]").

366 Ninety-eight determinations in 2016, 261 in 2017, and 547 in 2018. 10/7/16 Auditor's First Report on Purdue's ADD Program (PPLP004473667) at -668; 10/20/17 Auditor's Second Report on Purdue's ADD Program (PPLP004473709) at -711; 10/19/18 Auditor's Third Report on Purdue's ADD Program (PPLP004473738) at -742.

367 10/19/18 Auditor's Third Report on Purdue's ADD Program (PPLP004473738) at -741.

368 10/19/18 Auditor's Third Report on Purdue's ADD Program (PPLP004473738) at -749. In March 2017, Purdue had hired outside counsel, Spears Manning, to assist Purdue with all ADD determinations. Spears Manning was responsible for analyzing information collected as to each reported prescriber, interviewing relevant sales representatives, and drafting an initial recommendation as to whether Purdue should continue calling the prescriber. *See* Oct. 20, 2017 Auditor's Second Report on Purdue's ADD Program (PPLP004473709) at -717.

369 *In the Matter of Endo Solutions Inc. and Endo Pharm. Inc.*, Assurance No. 15-228 (Mar. 1, 2016).

370 *See* 6/10/16 Email to Board (PPLPC011000106533).

223. In 2003, Purdue shared with The Government Accountability Office ("GAO"). the number of ADD investigations the Company had conducted (483), the number of prescribers it had placed in Region Zero (197), and the number of those prescribers whom Purdue had referred to legal, medical, or regulatory authorities (39).[371]

224. Later that year, the GAO issued a report to Congress entitled PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM. [372] This 2003 GAO report recognized that "Purdue has initiated drug abuse and diversion education programs, taken disciplinary actions against sales representatives who improperly promote OxyContin, and referred physicians who were suspected of improperly prescribing OxyContin to the appropriate authorities" and that, "[a]s of September 2003, Purdue—through its own investigations—had identified 39 physicians and other health care professionals who were referred to legal, medical, or regulatory authorities for further action. Most of the 39 referrals stemmed from reports by Purdue's sales force."[373] The 2003 GAO report recommended that the FDA encourage other pharmaceutical manufacturers to develop "a strategy for monitoring the use of these drugs and identifying potential abuse and diversion problems."[374]

225. In 2011, Purdue again provided information about its ADD Program to the GAO, and the 2011 GAO report that followed included no negative feedback on it.[375]

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371 9/22/03 Email from Ted Hester with Attachment (BATES No. 9101439815).

372 U.S. GEN. ACCOUNTING OFFICE, GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (2003).

373 *Id*. at 34, 41.

374 *Id*. at 42.

375 *See* U.S. GEN. ACCOUNTING OFFICE, GAO-12-115, PRESCRIPTION PAIN RELIEVER ABUSE; AGENCIES HAVE BEGUN COORDINATING EDUCATION EFFORTS, BUT NEED TO ASSESS EFFECTIVENESS 38-39 (2011).

226. In 2006, Purdue fully described its ADD Program to the DOJ in connection with its 2007 settlement and plea agreement.[376] Purdue explained that it had "worked with law enforcement to identify specific indicia that might suggest misconduct, such as an unusually high number of patients paying cash for their prescriptions, physician's parking lots with unusually high numbers of cars with out-of-state license plates, or sudden, unexplained changes in a doctor's prescribing habits," and that sales representatives were instructed not to call the reported prescriber until the Law Department "had conducted an investigation."[377] Purdue also reported that the program had, as of 2006, resulted in 1160 reports to the Law Department, with more than 560 do-not-call decisions and more than 50 cases referred to medical, legal or regulatory authorities for investigation.[378]

227. The 2007 CIA required the OIG to review reports detailing how Purdue monitored its sales representatives for compliance with Purdue's Promotion Monitoring Program ("**PMP**"). The PMP was the process through which District Managers monitored sales representatives' interactions with HCPs and compliance with Purdue policies, including the ADD Program.[379] As the IRO reported to the OIG in 2009 and 2011, the PMP required District Managers to monitor sales representatives for (1) their knowledge of indicators of possible diversion by healthcare professionals, and (2) filing reports as required under the ADD

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376 *See* Description of Reporting Suspicious Prescribers (PPLPUCC9002443722); PPLP's ADD Program Background (PPLPC031001431032).

377 *See* Description of Reporting Suspicious Prescribers (PPLPUCC9002443722) at -723.

378 *Id*.

379 CIA at §III(D)(1)(b) & Appendix B §II(A)(7); IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 2 (PPLP004433812) at -815, -990-91; IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4 (PPLPC021000573227); IRO's Promotional and Product Services Transactions Engagement, Reporting Period 4 (PPLP004432560).

Program.[380] After reviewing these reports and receiving other requested information, the OIG certified Purdue's compliance with the CIA.[381]

228. Purdue met with the DEA several times to discuss its anti-diversion efforts.

229. On December 9, 2011, and October 16, 2013, Purdue gave presentations to the DEA concerning the reduction in abuse and diversion resulting from introduction of ADF OxyContin.[382]

230. Purdue met with the DEA multiple times to discuss the ADD Program in 2011.[383] In April and October of 2011, Purdue discussed with the DEA the abuse deterrent formulation of OxyContin (also called "ORF") and received feedback from DEA that "ORF has made a tremendous difference," "No longer hear about OxyContin from field offices," and "ORF is saving lives."[384] At the April 2011 meeting, Purdue discussed "ADD (and SOP 1.7.1) in general"—which the "DEA participants were very interested in learning more about"—and described "our efforts in depth, including training and expectation of the field reps."[385]

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380 9/25/09 Second Annual Report under CIA (PPLPC063000000289) at -300; IRO's Report on Promotional and Product Services Systems Engagement Reporting Period 2 (PPLP004433812) at -836; 9/23/11 Fourth Annual Report under CIA (PPLPC032000397973) at -984; IRO's Report on Promotional and Product Services Systems Engagement, Reporting Period 4 (PPLPC021000573227).

381 4/1/10 OIG Letter to Purdue (PPLP004250164); 3/8/12 OIG Letter to Purdue (PPLP004428603).

382 *See* 12/9/11 Presentation entitled "Epidemiology studies of Reformulated OxyContin's effect on opioid abuse" (PPLPC019000618954); 10/16/13 Presentation entitled "Update on Findings Regarding Reformulated OxyContin" (PPLPC020000725746) at -747.

383 *See* PPLP ADD Program Background (PPLPC031001431032).

384 2012 Budget Presentation to Board (PPLPUCC9011086649) at slide 6.

385 *See* 4/12/11 email from Jack Crowley describing meeting with DEA (PPLPC053000051168) at -170. A Purdue email recapping that meeting reported that the DEA told Purdue that its abuse and diversion detection efforts were "ahead of the curve—way ahead of any other manufacturer—light years ahead." *Id.*

231. In addition, in 2010 the Board was informed that DEA closed a "product diversion investigation which had been opened since early 2010,"[386] and in 2009 the Board learned that DEA inspected Purdue's Wilson and Coventry manufacturing sites and found no deficiencies.[387]

232. In 2012, Purdue met with the National Institute of Drug Abuse, the Office of National Drug Control Policy, and CDC to discuss the ADD Program.[388]

J. *Purdue Shared ADD/Region Zero Information With Regulators*

233. Between 2002 and 2018, Purdue referred at least 222 Region Zero prescribers to the DEA, including 82 in April 2011 alone.[389]

234. Between 2013 and 2015, Purdue supplied the names of 774 Region Zero prescribers to 25 regulators in 17 states, as follows:

STATE OR STATE AGENCY	DATE	# OF HCPS DISCLOSED	SOURCE
1. Alabama State Board of Medical Examiners	3/11/14	23	PPLP004437472
2. Arizona Board of Osteopathic Examiners in Medicine and Surgery	2/28/14	11	PPLP004437482
3. California Board of Podiatric Medicine	9/26/13	1	PPLPUCC9011507904
4. California Board of Registered Nursing	9/25/13	3	PPLP004437542
5. California Dental Board	9/12/13	1	PPLPC051000189775
6. California Medical Board	9/11/13	49	PPLPC049000079268

386 3Q 2010 Board Report (PPLP004366991) at -998.

387 *See* Jan. 21, 2010 Board Agenda (PPLPC044000023970) at -4004.

388 *See* PPLP ADD Program Background (PPLPC031001431032).

389 *See* 4/12/11 email from Jack Crowley describing meeting with DEA (PPLPC053000051168) at -170. Jack Crowley, Purdue's Executive Director of Controlled Substance Act Compliance and a 28-year veteran of the DEA, also "routinely" made informal referrals to the DEA. *See* Jan. 10, 2019 Deposition Transcript of Crowley, *In re: National Prescription Opiate Litigation*, No. 17-md-2804, ECF No. 1976-8 at 42:8-10, 287:23-25.

STATE OR STATE AGENCY	DATE	# OF HCPS DISCLOSED	SOURCE
	9/25/13	113	PPLPC051000189745
7. California Osteopathic Medical Board	9/25/13	13	PPLPC051000189739
8. California Physician Assistant Board	9/26/13	9	PPLPUCC9011507902
9. Georgia Composite Medical Board	2/27/14	66	PPLP004437620
10. Illinois Department of Financial and Professional Regulation	2/12/14	34	PPLP004437654
11. Kansas State Board of Healing Hearts	3/4/14	9	PPLP004437673
12. Nevada State Board of Medical Examiners	8/27/13	35	PPLPC049000076533
	8/11/15	7	PPLPUCC9011512808
	5/17/16	6	PPLPUCC9011562267
13. Nevada State Board of Osteopathic Medicine	9/26/13	6	PPLPUCC9011507906
14. Nevada State Board of Pharmacy	9/3/13	1	PPLPC049000079271
15. New Jersey Office of Attorney General	11/8/13	45	PPLP004437814
16. North Dakota State Board of Medical Examiners	3/7/14	2	PPLP004437795
17. Oregon Medical Board	5/20/14	19	PPLPUCC9011455002
18. Pennsylvania Department of State, Bureau of Professional/Occupational Affairs	2/28/14	98	PPLP004437994
19. Rhode Island Board of Medical Licensure & Discipline	3/11/14	16	PPLP004438019
20. Tennessee Office of Attorney General	10/15/13	75	PPLP004438085
21. Virginia Department of Health Professions	2/19/14	64	PPLP004438105
22. West Virginia Board of Medicine	2/27/14	25	PPLP004438134
23. West Virginia Board of Osteopathic Medicine	2/27/14	7	PPLP004438138
24. Wisconsin Department of Safety & Professional Services	2/25/14	33	PPLP004438118
	4/28/14	N/A	PPLP004438113
25. Wyoming Board of Medicine	2/26/14	3	PPLP004438157

STATE OR STATE AGENCY	DATE	# OF HCPS DISCLOSED	SOURCE
TOTAL		**774**	

235. In 2013, Purdue furnished the names of Region Zero HCPs in Pennsylvania, New Jersey, and Delaware to the U.S. Attorney for the Eastern District of Pennsylvania.[390] In 2014, Purdue twice provided Region Zero information to the U.S. Senate Caucus on International Narcotics Control.[391]

236. Purdue's 2008-2010 reports to the 27 Consent Judgment Attorneys General included the number of ADD investigations conducted, the number of HCPs or pharmacies placed in Region Zero and reported to law enforcement, and how many of those HCPs were high, mid-, and low-level OxyContin prescribers, or who did not prescribe OxyContin at all, as follows:[392]

390 9/13/13 Letter to Eastern District of Pennsylvania AUSA (PPLPC049000079240).

391 1/7/14 Letter to Senators (PPLPC049000103061); 3/12/14 Letter to Senators (PPLPC049000103152).

392 *See* 5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000041921) at -928; 5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PWG004407107) at -113; 5/7/10 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000064681) at -688. The following is a summary of these reports:

	5/08 Certification	5/09 Certification	5/10 Certification	Total
HCPs Investigated	**226**	**239**	**480**	**945**
High	*42*	*88*	*140*	*270*
Medium	*39*	*49*	*102*	*190*
Low	*143*	*81*	*157*	*381*
No OxyContin	*not reported*	*21*	*81*	*102*
Region 0 Placements	**116**	**225**	**300**	**641**
Referral to authorities	4	7	11	22

237. In May 2008, Purdue reported that, between May 7, 2007 and May 2, 2008, its Law Department conducted 226 Region Zero investigations; that in 116 of the cases, Purdue decided that the sales reps should not call on the HCP; that in four of those cases, Purdue initiated a referral to legal, medical or regulatory authorities; and that, in many of the remaining cases, "Purdue was already aware that an investigation was pending" and "actively cooperated with the investigation by furnishing documents, answering questions, or providing potential witnesses."[393]

238. In May 2009, Purdue reported that, in the prior year, its Law Department had conducted 239 investigations; stopped marketing to the HCPs in 225 of those cases; referred 7 to the authorities; and was aware, in many of the other cases, that the HCPs were the subject of a pending investigation, with which Purdue actively cooperated.[394]

239. In May 2010, Purdue reported that, in the prior year, its Law Department had conducted 480 investigations; stopped marketing to the HCPs in 300 of those cases; referred 11 HCPs to the authorities; and was aware that, in many of the other cases, the prescribers were the subject of a pending investigation with which Purdue actively cooperated.[395]

240. The Consent Judgments barred Purdue from including in these reports "the names of any specific Health Care Professionals,"[396] but states had the right to request Region Zero

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393 5/7/08 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000041921) at -928.

394 5/7/09 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PWG004407107) at -113.

395 May 7, 2010 Letter from Purdue Counsel to the Ohio AG attaching Certification of Compliance (PPLPC026000064681) at -688.

396 Ky. Consent Judgment ¶24(e).

information from Purdue at any time,[397] and Purdue provided information to the states whenever requested.[398]

K. *The Board Was Presented Data Showing That Diversion, Abuse, And Prescriptions By Region Zero HCPs Fell Substantially After Abuse-Deterrent OxyContin Was Introduced In 2010*

241. In August 2010, Purdue launched reformulated OxyContin, the first abuse-deterrent opioid product ever approved by the FDA. While the reformulated tablet is not abuse-proof (multiple pills can be ingested orally despite the label's warnings), it is abuse deterrent because it is difficult to crush and, when crushed, does not dissolve into a powder that is capable of being inhaled or snorted.[399]

242. The Board received extensive data presented by management following the introduction of the abuse-deterrent formulation in 2010 showing that the new formulation produced a substantial reduction in (1) diversion, (2) abuse and (3) the number of prescriptions written by prescribers the Company had placed in Region Zero.

243. Purdue's management provided the Board with statistics, based on third-party data, showing that diversion fell substantially following the introduction of the abuse-deterrent

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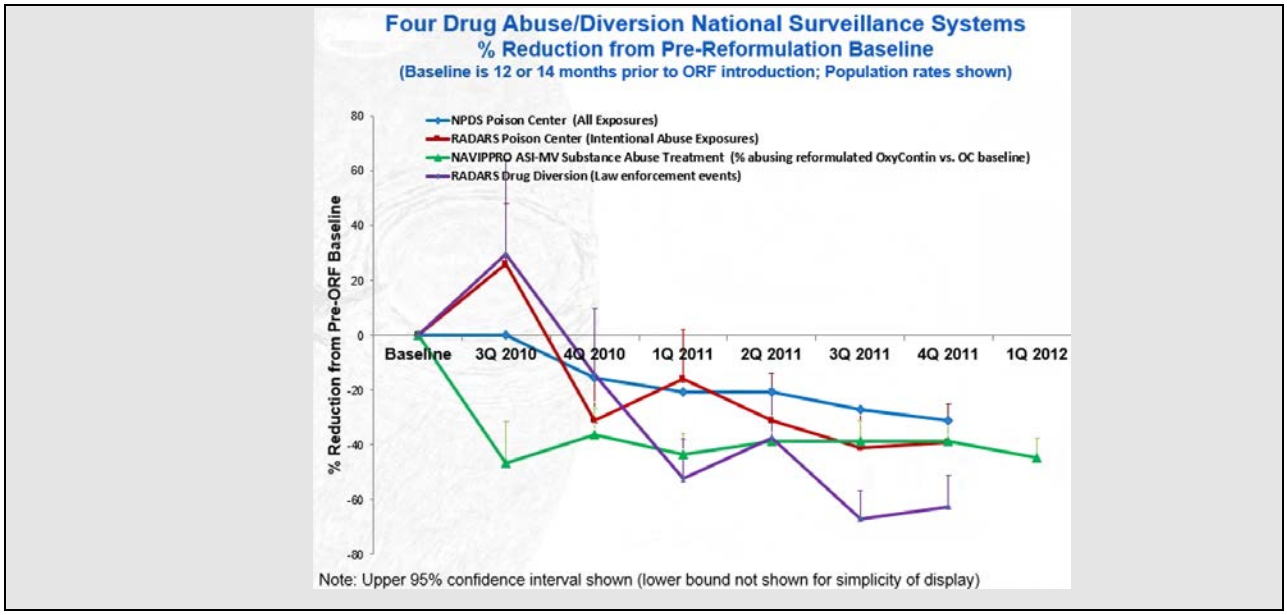
397 *Id.* ¶24(f) ("upon written request, the [AGs] may obtain state-specific information as described in subsection (e)").

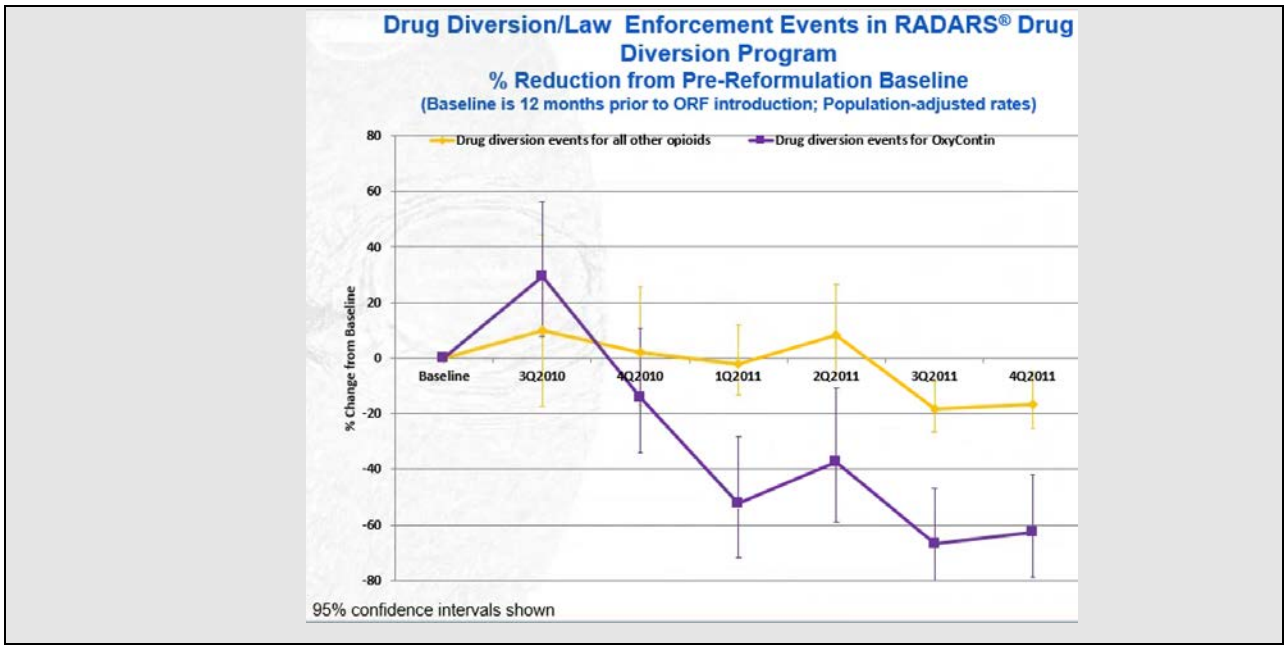
398 *See, e.g.*, May 18, 2009 Letter from Purdue Counsel to Virginia Attorney General's Office (PPLPC051000075710) (providing a list of Virginia healthcare professionals on Purdue's "Do Not Call" list).

399 *See* FDA Press Release, *FDA approves abuse-deterrent labeling for reformulated OxyContin* (Apr. 16, 2013): "The FDA has determined that the reformulated product has abuse deterrent properties. The tablet is more difficult to crush, break, or dissolve. It also forms a viscous hydrogel and cannot be easily prepared for injection." https://web.archive.org/web/20130419012709/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm348252.htm.

formulation. This is shown, for example, on the following two slides that management presented to the Board at the June 18, 2012 Board Meeting:

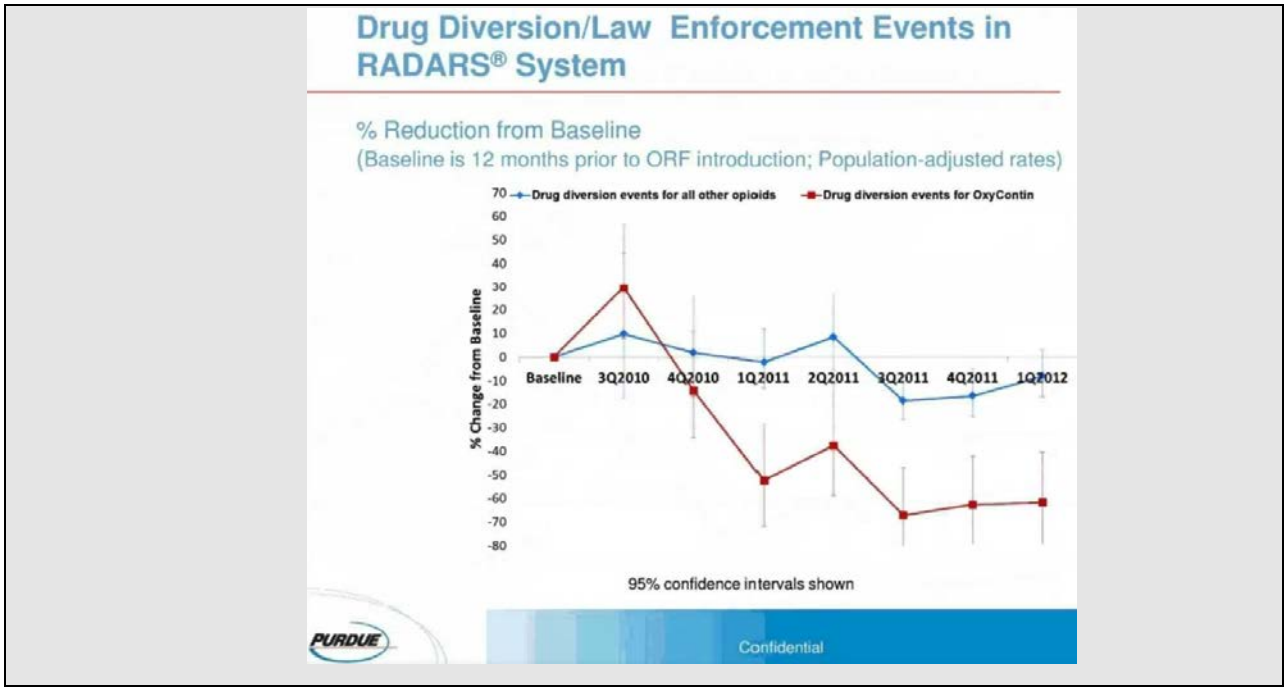


(Above) June 2012 Presentation to Board (PPLPC057000011194) at slide 9.



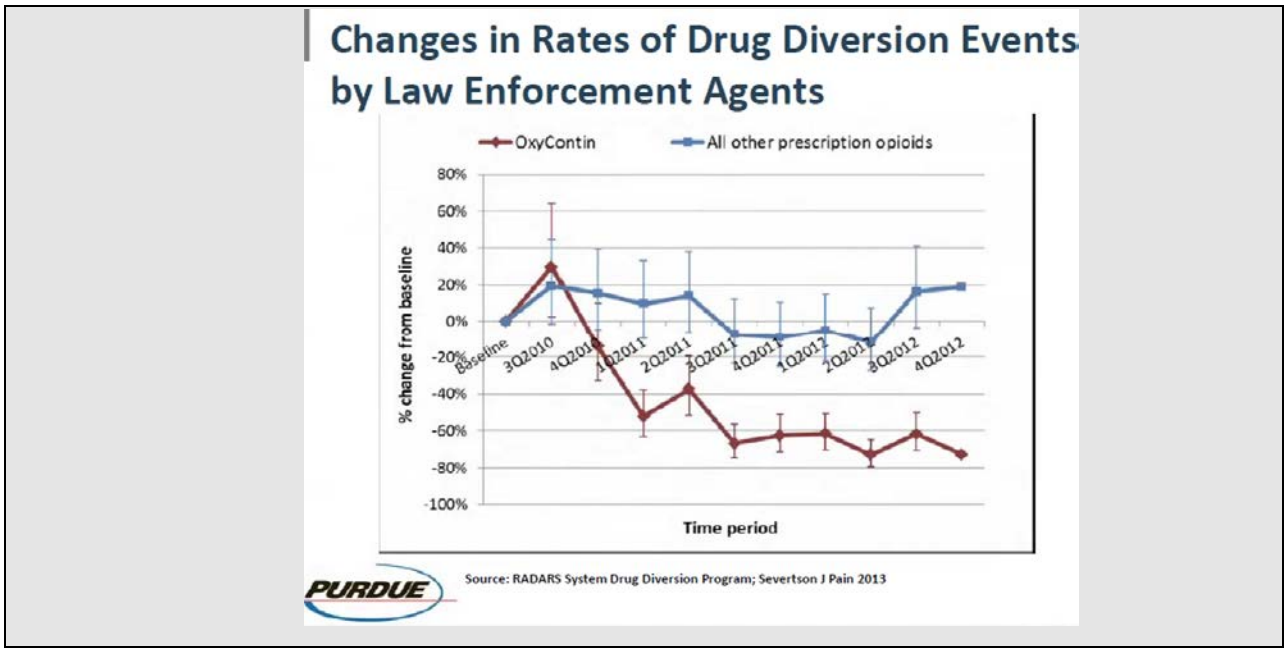
Id. at slide 11.

244. Management presented additional data documenting this reduction in diversion at the March 21, 2013 Board meeting, including this slide:



Mar. 21, 2013 Board Agenda (PPLPC044000041897) at -964.

245. Updated data showing the same dramatic diminution in diversion were presented to family members at the November 16, 2013 beneficiaries meeting. *See, e.g.* Nov. 16, 2013 Presentation to Beneficiaries (PPLPC051000193984) at -4069:



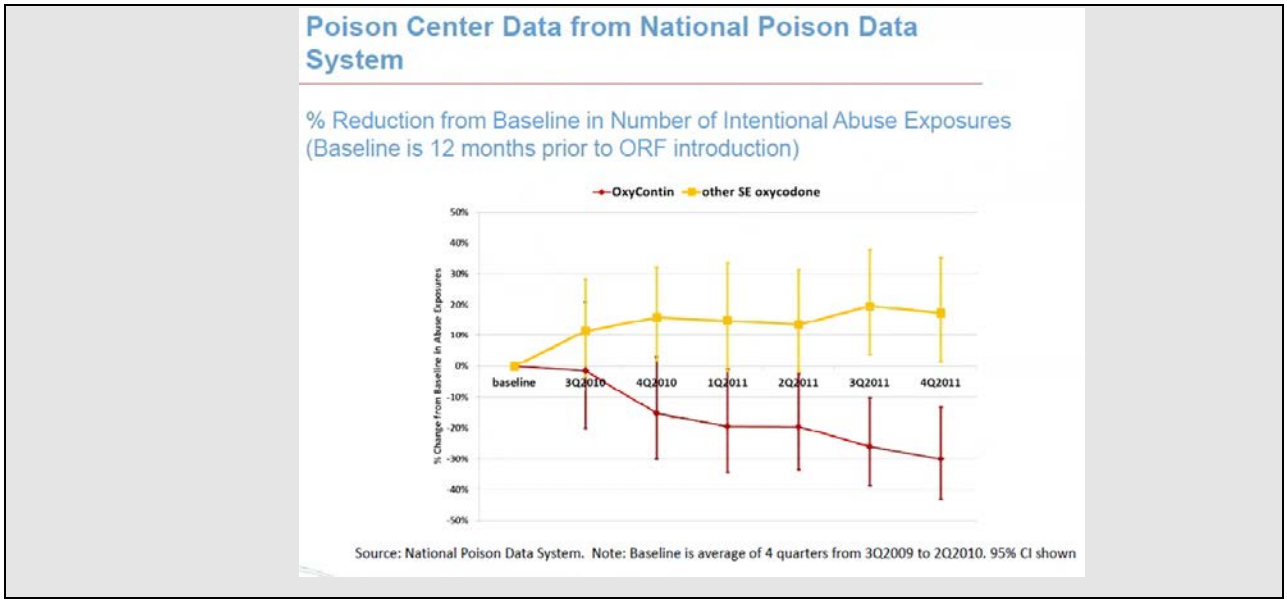
246. Purdue also reported to the DEA data showing that diversion fell substantially after ADF OxyContin was introduced.[400] In November 2011, the Board was informed that the chief of the Regulatory Section of the DEA's Office of Diversion Control had reported to Purdue executives that the reformulation "*has made a tremendous difference*" and "*is saving lives*," and that the DEA "*[n]o longer hear[s] about OxyContin from field offices*."[401]

247. In addition to the striking drop in diversion, management also presented data to the Board showing a similar "Meaningful Reduction in Abuse" of OxyContin following

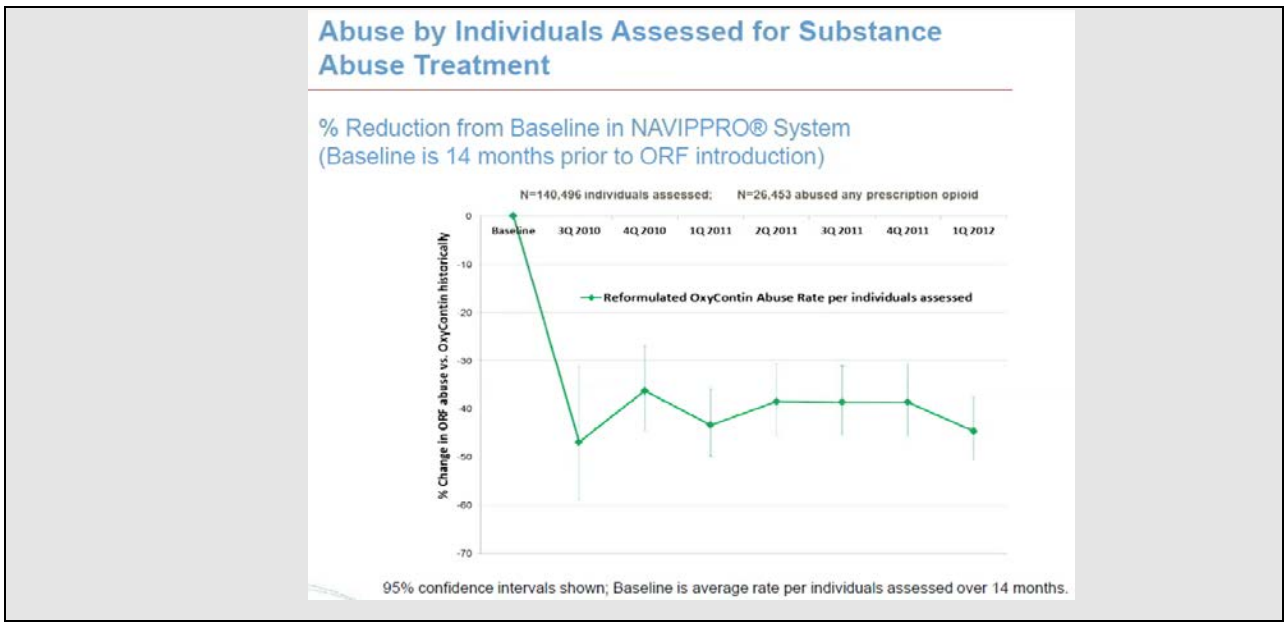
400 12/9/11 Presentation entitled "Epidemiology studies of Reformulated OxyContin's effect on opioid abuse" (PPLPC019000618954).

401 Nov. 2011 Budget Book (PPLPUCC9011086649) at slide 6.

introduction of the abuse-deterrent formulation.[402] For example, at the March 21, 2013 Board meeting management presented, among others, the following three slides:

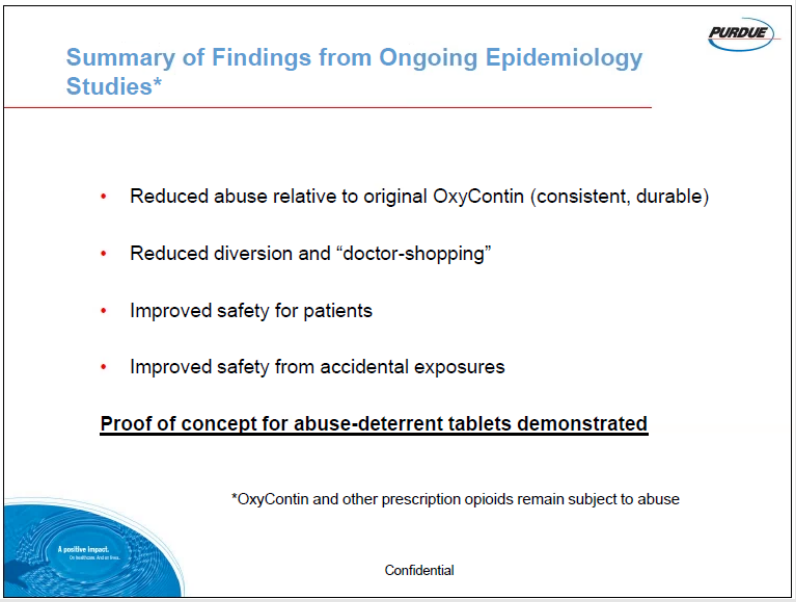


(Above) Mar. 21, 2013 Board Agenda (PPLPC044000041897) at -962.



Id. at -961.

402 7/25/13 Board Agenda (PPLP004409781) at -860.



Id. at -968.

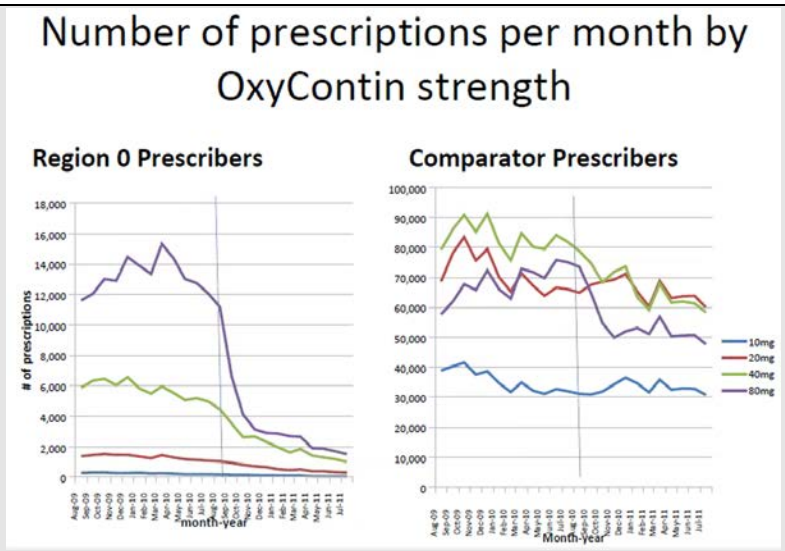
248. At management's November 16, 2013 beneficiaries' presentation to Sackler family members, management presented additional data demonstrating the reduction in abuse. *See, e.g.*, Nov. 16, 2013 Presentation to Beneficiaries (PPLPC051000193984) at -4067:

Reported abuse of OxyContin among abusers of any prescription opioid in the NAVIPPRO ASI-MV System
(June 2009 - Dec 2012)

Original & Reformulated OxyContin	Before period (%)	After period (%)	Pre-post relative change	95% CI	P-Value
Any route	25	19	-24	(-27; -20)	<.0001
Oral	13	14	+2	(-3, 8)	0.432
Non-Oral	19	11	-42	(-45, -38	<.0001

Before period = June 2009 through August 8, 2010
*After period = August 9, 2010 through December 31, 2012 Only ORF (and not OC) is included in this column.

249. In addition to the marked reduction of both diversion and abuse, the Board was informed that there was a sharp drop in the number of prescriptions written by prescribers whom Purdue had placed on its No-Call (Region Zero) list. This was reflected in data that management sent the Board with Executive Committee Notes dated October 11, 2011. *See, e.g.*, Attachment to Oct. 25, 2011 Exec. Comm. Notes Sent to Board (PURDUE-COR-00032186) at slide 10:



VI. DURING THE RELEVANT PERIOD, THE FORMER DIRECTORS DID NOT PARTICIPATE IN DECISIONS ABOUT WHAT PURDUE'S MARKETING WOULD SAY, BUT UNDERSTOOD THAT IT WAS LAWFUL AND WAS TARGETED AT A LEGITIMATE MARKET

250. The Sales and Marketing departments developed all of the Purdue's marketing and advertising materials, and the Legal, Regulatory, and Medical Affairs departments were required to review and unanimously approve all such materials before first use. *See* Material Review Process SOP (PPLP004368497). The Board received some marketing material for informational purposes but was never asked to approve or disapprove it.

251. No evidence has been adduced that any Former Director wrote, edited, commented on, approved or uttered any piece of Purdue marketing during the Relevant Period.

252. No evidence has been adduced that during the Relevant Period any marketing was submitted to the Board for approval.

253. No evidence has been adduced that during the Relevant Period the PPI Board voted on the contents of Purdue's marketing.

254. No evidence has been adduced that any piece of Purdue marketing was changed or adopted because of any Board decision or the input of any PPI Board member.

255. Notes from a 2008 Purdue Executive Committee remark that "the Board ha[d] little other opportunity" outside of budget meetings "to see the detailed work of the Sales and Marketing group...." [403]

256. In the budget meetings, as well, the Board was never asked to review or approve the substance of any marketing initiative.[404]

257. David Sackler testified, "management would make presentations to the board on sales and marketing," but "there wasn't a lot of feedback given."[405]

258. Numerous witnesses confirm that the Former Directors had minimal contacts with most Purdue employees outside of board meetings. For example:

- Purdue's Director of Advocacy in Public Affairs Department, then Executive Director of Healthcare Alliance Department, who worked at Purdue 2001–2018, testified that she met the Sacklers "once or twice" in her 18 years at Purdue at board meetings and a holiday party.[406]

- Purdue's Senior Director of Research & Development from 2000 onwards testified that "the only meetings that I had that included Dr. Richard ... were board meetings, where I was as the head of regulatory or even before then as the head of a particular project reporting to the board on development programs."[407]

- One employee in charge of Government Relations, when asked whether Richard Sackler was "involved in setting up the Pain Care Forum," testified "Not at all, to my knowledge. … I don't think I ever had a personal conversation with Richard

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403 *See* 9/12/08 Executive Committee Notes (PPLPC053000030108).

404 *See, e.g.*, Nov. 2010 Budget Presentation (PPLP004404901) at -919-957; Nov. 2011 Budget Presentation (PPLP004406990) at -3201-3344; Nov. 2013 Budget Presentation (PPLP004409973) at -987-030.

405 David Sackler Dep. Tr. at 245:6-17.

406 Pamela Bennett Tr. at 29:4–9, 115:18–21, 116:19–23 237:22-239:11, *In re Nat'l Prescription Opiate Litig.*, No. 1:18-md-2804 (N.D. Ohio).

407 Richard Fanelli 30(b)(6) Tr. at 314:18-316:4, 427:17–428:2, 430:7–9, *In re Nat'l Prescription Opiate Litig.*, No. 1:18-md-2804 (N.D. Ohio).

about the Pain Care Forum, none that I remember. … I might have mentioned the Pain Care Forum at a board meeting.").[408]

- One employee who worked at Regulatory Affairs, then Drug Safety and Pharmacovigilance, then Product Monitoring, at Purdue 1992–2017, was asked during her deposition "was Richard Sackler involved in the day-today management of the company, of Purdue in your experience?" She testified "In my experience, I had very little to do with him. So I don't know."[409]

- Counsel for some Claimants asked one key opinion leader, who received payments from Purdue, whether he "ever met any of the Sacklers" or "ever had any telephone or email discussions with them." "Not that I recall," was his answer to both questions.[410]

259. Some Claimants have alleged that Richard Sackler and other directors engaged in micromanagement of Purdue's marketing. These allegations and their supposed factual bases are addressed below.

A. *Board Reports*

260. As the foregoing reflects, during the Relevant Period, the Former Directors received numerous reports on many topics from Purdue's management informing them about Purdue's activities.[411]

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[408] Burt Rosen Tr. at 27:22–28:2, 39:12–13, 65:1-16, 302:20–22, *In re Nat'l Prescription Opiate Litig.*, No. 1:18-md-2804 (N.D. Ohio).

[409] Lee Ann Storey Tr. 28:2–29:3, 88:14-90:10, *In re Nat'l Prescription Opiate Litig.*, No. 1:18-md-2804 (N.D. Ohio).

[410] Perry Fine Dep. Tr. at 82:9-21, *In the Matter of Purdue Pharma L.P.*, CDP Legal File No. CP-2019-005, DCP Case No. 107102 (Utah Div. of Consumer Prot.).

[411] July 13, 2005 Board Report (PPLPC026000024332); 1Q 2006 Board Report (PPLPC036000067805); 2Q 2006 Board Report (PPLPC026000027526); 3Q 2006 Board Report (PPLPC036000073187); 4Q 2006 Board Report (PPLP004367696); 1Q 2007 Board Report (PPLP004367733); 2Q 2007 Board Report (PPLP004366645); 3Q 2007 Board Report (PPLPC012000157402); 4Q 2007 Board Report (PPLP004367604); 1Q 2008 Board Report (PPLP004367134); 2Q 2008 Board Report (PPLP004367297); 3Q 2008 Board Report (PPLP004367232); 4Q 2008 Board Report (PPLP004367067); 1Q 2009 Board Report (PPLP004367262); 2Q 2009 Board Report (PPLPC012000233231); 3Q 2009 Board Report (PPLP004367330); 4Q 2009 Board Report (PPLP004367162); 1Q 2010 Board Report (PPLP004317547); 2Q 2010 Board Report (PPLP004367018); 3Q 2010 Board Report (PPLP004366991); 4Q 2010 Board Report (PPLP004366955); 1Q 2011 Board Report

261. None of the Board Reports contains any evidence that the Former Directors were participating in decisions about what Purdue's marketing should say. Not once did management include in these reports a request that the Former Directors vote on or evaluate proposed marketing materials.

262. Claimants have asserted that some Board Reports show that the Former Directors "oversaw Purdue's strategy to pay high prescribers to promote Purdue opioids." Complaint ¶182, *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, C.A. No. 1884-cv-1808 (Mass. Super. Ct., Suffolk Cty. Jun. 12, 2018) ("MA AG OC"); *see also* First Amended Complaint ¶388, *State of New York v. Purdue Pharma L.P.*, Index No. 400016/2018 (N.Y. Sup. Ct. Suffolk Cty.) ("NY AG FAC"). The cited Board Reports say nothing about a "strategy to pay high prescribers," but they did inform the Board of new reporting requirements and spending limits under the "Sunshine Act"[412] and advise the Board that Purdue's speaker programs had "appropriate controls," including "a live monitoring process" and an "expert consultant on Fair Market Value compensation of speakers," to ensure compliance.[413]

263. Claimants have alleged that one of the Board Reports shows that the directors "oversaw Purdue's push to steer patients away from safer alternatives." MA AG OC ¶188; *see*

(PPLPC012000322426); 2Q 2011 Board Report (PPLP004366913); 3Q 2011 Board Report (PPLP004366871); 4Q 2011 Board Report (PPLPC012000362869); 1Q 2012 Board Report (PPLPC012000374791); 2Q 2012 Board Report (PPLPC012000387069); 3Q 2012 Board Report (PPLP004366816); 4Q 2012 Board Report (PPLP004366760); 1Q 2013 Board Report (PPLP004367540); 2Q 2013 Board Report (PPLPC012000433388); 3Q 2013 Board Report (PPLPC002000186911); 4Q 2013 Board Report (PPLPC002000181035).

412 2Q 2013 Board Report (PPLPC012000433388) at -436.

413 2Q 2011 Board Report (PPLP004366913) at -940; *see also* 3Q 2011 Board Report (PPLP004366871) at -897 ("implemented a live monitoring process. Approximately 10% of all speaker programs have an independent monitor in attendance to identify and report any compliance issues. To date no substantive concerns have been identified.").

also NY AG FAC ¶388. The cited Board Report explained why some insurers would not cover Hysingla, an as-yet unlaunched product, and said nothing about a marketing "push" away from safer alternatives.[414]

264. Claimants cite one of the Board Reports as evidence that the "Sacklers directed Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign …" NY AG FAC ¶394; *see also* MA AG FAC ¶335. The cited Board Report simply noted that Purdue had expanded its sales force in connection with the upcoming launch of Purdue's new product, Butrans.[415]

265. Claimants have asserted that the Board Reports show that the Board "agreed" to "a 'Key Initiative' [ ] to get patients to 'stay on therapy longer.'" NY AG FAC ¶398; *see also* MA AG FAC ¶433. The cited pages of the Board Report discussed net sales (p. 3) and explained an adherence program to help patients take Butrans (a Schedule III transdermal patch) as prescribed (pp. 9, 22).[416]

B. *Documents Related to Butrans (A Schedule III Opioid Patch)*

266. Purdue launched Butrans in 2011 and, until February 2018, Purdue's staff promoted the product to trained HCPs.

267. Butrans is a skin patch that contains buprenorphine, a Schedule III controlled substance[417] that is subject to less strict regulation than OxyContin and other Schedule II opioids

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414 6/6/13 Managed Care Board Slides (PPLPC063000016119) at -137 ("HYD Payer Research … Payers will not value a new hydrocodone product until they more fully understand the true incidence of opioid combination acetaminophen-related liver toxicity.").

415 4Q 2010 Board Report (PPLP004366955) at -960.

416 4Q 2013 Board Report (PPLPC002000181035) at -043-44.

417 *See* 2014 Butrans FDA-Approved Label at 7, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf.

because it has a lower abuse or dependence potential.[418] According to the federal Substance Abuse and Mental Health Services Administration's ("**SAMHSA**"), "buprenorphine has unique pharmacological properties that help: [d]iminish the effects of physical dependency to opioids, such as withdrawal symptoms and cravings; [i]ncrease safety in cases of overdose; [and l]ower the potential for misuse."[419] Additionally, unlike OxyContin,[420] Butrans has a ceiling dose. The FDA-approved label for Butrans sets the upper limit for a Butrans prescription at 20 mcg/hour.[421]

268. Many Claimants have claimed that Purdue was trying to convince HCPs to prescribe "higher and higher doses" of opioids (*see, e.g.*, MA AG FAC ¶¶67, 857). These allegations do not fit Butrans, with its ceiling dose—higher and higher doses could not be prescribed.

269. The Massachusetts AG alleged that a presentation by Purdue management told the Board that "sales reps would try to switch patients to opioids from NSAIDs." MA AG FAC ¶306. In fact, the cited presentation informed the Board that the "proposed placement in clinical practice" for Butrans included patients for whom NSAIDs were not working because "pain is not well controlled" using an NSAID or because an "NSAID … [is] not tolerated."[422] The

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418 *See Drug Scheduling*, DRUG ENFORCEMENT ADMINISTRATION, https://www.dea.gov/drug-scheduling.

419 *See Buprenorphine*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine.

420 *See* Mar. 2021 OxyContin FDA-Approved Label at pdf p. 36 ("Like all full opioid agonists, there is no ceiling effect to analgesia for oxycodone."), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022272s046lbl.pdf.

421 2014 Butrans FDA-Approved Label at pdf p. 5 ("The maximum BUTRANS dose is 20 mcg/hour. Do not exceed a dose of one 20 mcg/hour"), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021306s015s019lbl.pdf.

422 7/22/10 Butrans Commercial Strategy Plan Board Presentation (PPLPC018000404193) at slide 17.

presentation also informed the Board that Purdue would provide prescribers "[a]ppropriate fair balance information … including contraindications, warnings, precautions and safety information," and would "[p]roperly educate healthcare professionals on … [t]he full prescribing information and appropriate use of Butrans."[423] Moreover, all of this occurred in 2010, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2010.

270. The Massachusetts AG alleged that the Board received a report that informed them that Purdue sales representatives focused on physicians that "would be most susceptible to sales reps lobbying to prescribe more opioids" and "push[ed] opioids for elderly patients with arthritis." MA AG FAC ¶¶341-42. In fact, the cited email does not mention "arthritis," "pushing opioids," or the "susceptibility" of physicians.[424] The email informed the Board that Purdue was focused on Butrans "and what need[ed] to be done to increase [its] growth" after its launch earlier that year.[425] The email indicated that Purdue was working to grow Butrans sales by "[i]mproving physician targeting," "[i]ncreasing call frequency", and "[i]mprov[ing] specific patient focus on calls."[426] Moreover, this email exchange occurred in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

271. The Massachusetts AG alleged that Purdue staff told Richard Sackler that Purdue was "pushing opioids for elderly patients with arthritis ('proper patient selection') and encouraging doctors to use higher doses of opioids ('quick titration')." MA AG FAC ¶376. In fact, the cited document does not mention the elderly, arthritis or encouraging doctors to use higher doses of opioids. The document says that Butrans sales statistics had improved and that

423 *Id.* at slides 20, 47.

424 5/25/11 Email to Board (PPLPC012000326017).

425 *Id.*

426 *Id.*

David Rosen guessed "the breakthrough … is related to the messages coming out of the district meetings and [their] renewed discussion around proper patient selection, supplemental analgesia and quick titration."[427] Moreover, this email was sent in March 2012, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for this period.

C. *McKinsey's Evolve To Excellence Advice*

272. In November 2012, Purdue's management told the Board about plans to use as a key promotional point in the future the anticipated approval by the FDA of a new label recognizing ADF OxyContin's abuse deterrent properties. The goal, as articulated by management, was to encourage responsible HCPs to prescribe OxyContin over competitors' prescription opioids, which did not have similar abuse deterrent properties.[428]

273. Purdue's management hired McKinsey in conjunction with this effort.

274. Purdue's management made the decision to engage McKinsey around May 2013.[429]

275. McKinsey's advice to management resulted in the Evolve to Excellence (or "**E2E**") marketing program, which was intended to improve sales.

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427 3/28/12 Email from David Rosen (PPLPC012000371301).

428 *See, e.g.*, Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110) (listing Opportunities for Purdue's Sales and Marketing: "New formulation is favorably impacting abuse") at slide 13; *id.* at slide 25 (identifying "Tamper-Resistant Formulation" as an opportunity for OxyContin).

429 *See* Statement of services "effective as of May 28, 2013" (PPLPC051000178707); 4/10/13 Email from Russell Gasdia (PPLPC012000417566) (noting that decision to meet with McKinsey was the "result of several of [Gasdia's] colleagues pushing it"); 5/19/13 email from David Rosen (PPLPC012000424137).

276. The Board was not informed about management's decision to retain McKinsey until after the retention had taken place.[430]

277. The Board subsequently received memoranda prepared by McKinsey regarding its E2E advice.[431]

278. Board members first met with McKinsey consultants in August 2013.[432]

279. After the meeting, McKinsey consultants remarked on the Board's lack of knowledge about McKinsey's advice:

- "Board had not engaged on our work…. Dr. Richard had not read memo…"
- "We took them through both memos – some had read it, some had not. We went through exhibit by exhibit for about 2 hrs. They all clearly learned a lot and many asked good questions."

Id. (ellipses in original).

280. Notes from one October 2013 Board meeting reflect the Board's comments/questions in regard to the E2E project stating that Purdue's marketing and salesforce should be driven by a public mission of helping patients and physicians—to "not just push to obtain scripts ... do well by doing good."[433] The Board further commented:

> In terms of incentives, the salesforce (and indeed the entire organization) should be driven to be of high value to patients and physicians (and the healthcare system), and not simply to increase prescriptions for Purdue products.

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[430] 6/5/13 Email to the Board and Others (PPLPC057000014144) at -145 ("McKinsey has been engaged to work with Sales & Marketing to identify opportunities to improve performance of OxyContin.").

[431] 7/25/13 Board Agenda with McKinsey Report (PPLP004409781) at -871; 8/15/13 Board Agenda with McKinsey Report (PPLP004409890) at -892.

[432] 8/26/13 Email from Jeanette Park (MCK-MAAG-0112331).

[433] 11/1/13 Email from Gary Stiles re "Board Notes & Actions" (PPLPC012000449535) at -538.

11/18/13 Email from John Stewart re Budget Meeting Notes & Actions (PPLPC012000452389) at -392.

281. McKinsey said its advice presented an "upside" of ">$100 million in annual sales."[434] At the time, PPLP's sales exceeded $2 billion annually.[435]

282. The Board was told by McKinsey that its advice was about implementing "industry best practices"[436] at Purdue, by among other things targeting Purdue's sales efforts at high decile prescribers, who were considered more likely to prescribe Purdue's products.

283. The Board understood that E2E was aimed at persuading prescribers to switch appropriate patients from Purdue's competitors' products to Purdue opioids.[437]

284. Purdue's management presented data to the Board showing that there was an enormous legitimate market for Purdue's prescription opioids currently occupied by competitors

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[434] *See* 8/15/13 Board Agenda with McKinsey Report (PPLP004409890) at -892.

[435] *See* Nov. 2013 Budget Presentation (PPLP004409973) at -988; Aug. 2015 Budget Presentation (PPLPC051000265076).

[436] *See, e.g.*, 8/15/13 Board Agenda with McKinsey Report (PPLP004409890) at -907, -916 ("These ideas are primarily about implementing industry best practices in execution. These best practices can be adapted for Purdue and rolled out quickly.… Purdue's annual goal of 1400 calls per rep is below our observed industry best practices of 1700 calls per rep."); *see also* 7/25/13 Board Agenda with McKinsey Report (PPLP004409781) at -877, -879, -887 ("These ideas are primarily about implementing industry best practices in execution. These best practices can be adapted for Purdue and rolled out quickly.… Industry best practice targets physicians based on a composite value.... Best practice field force optimization requires a significant holistic approach....").

[437] *See, e.g.*, Nov. 2014 Budget Presentation to Board (PPLP004411368) at -409 (Purdue seeking to convert immediate-release opioid ("**IR**") prescriptions to extended-release OxyContin prescriptions ; *id.* at -413 (Purdue seeking to convert appropriate patients on "IR oxycodone to OxyContin" and to call on HCPs with a high "oxycodone to non-OxyContin switch rate"); 9/13/13 McKinsey Presentation (PPLPUCC9008739108) at -157 (McKinsey's presentations included a sample HCP who—after being called on by Purdue sales representatives—went from writing 23% of his ERO prescriptions as OxyContin in one year to 43% the next, with success defined as educating HCPs to consider whether OxyContin was a better option for some patients than the competitor opioids).

and explained that Purdue's marketing was aimed at persuading HCPs to prescribe Purdue opioids over competitors' medications. For example, the Board received a presentation showing that the competitive prescription analgesic market totaled more than $12.1 billion.[438] Purdue's opioid sales were approximately $2.9 billion at that time. *Id.* at 3. This left a prescription analgesic market of more than $9 billion that Purdue could expand into by taking market share from competitors.

285. The Board also received reports stating that OxyContin's decline was caused by factors in addition to, and separate and apart from, the abuse-deterrent formulation, including legislation and market events adversely affecting the Extended Release Opioids ("**EROs**") market generally. These included that the ERO market was shrinking; there was increased competition in the ERO market with new, competing long-acting opioids entering the market; new entrants were targeting OxyContin; generics were taking a higher proportion of the ERO market and of all opioid prescriptions.[439]

286. The Board was informed that 68% of immediate-release oxycodone conversions went to competing EROs and that Purdue was targeting the IR market, emphasizing OxyContin's abuse-deterrent properties in its marketing.[440]

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438 Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396109) at Slide 8.

439 9/13/13 McKinsey Presentation (PPLPUCC9008739108) at -120-21 (attributing 38% of the decline to the decline of the overall ERO market, 49% of the decline to a decline of the Branded ERO market, and 14% of the decline to OxyContin's loss in its share of the Branded ERO market); Nov. 2013 Budget Presentation (PPLP004409973) at -1004-08 (legislation, increased genericization, identifying competitive products); Nov. 2010 Sales & Marketing Presentation to Board (PPLP004404901) ("New long-acting, seeing-entity opioid entrants (i.e., Nucynta® ER, Remoxy®) thrent TRx [total prescription] market share..."); Oct. 2011 Full Budget Presentation (PPLPUCC003392177) at slide 276 ("Nucynta® ER is Targeting OxyContin® Tablets").

440 Nov. 2014 Budget Presentation to Board (PPLP004411368) at -408, -409, -412, -413.

287. Based on the foregoing and other information presented to the PPI directors, during the period 2013 to 2018, the Board understood that Purdue's opioids medications were serving a small portion of a large market.[441]

288. The Board was advised that E2E marketing emphasized OxyContin's abuse-deterrent properties.[442]

289. The Board understood that Purdue's Law Department considered evidence that a prescriber had stopped prescribing OxyContin following the introduction of ADF OxyContin to be suggestive of the possibility that the prescriber was issuing illegitimate prescriptions. The Board was told that Purdue's Law Department had, with the Epidemiology Department, "[d]evelop[ed] [a] model to attempt identification of suspicious prescribing patterns that warrant further investigation"[443] in order to determine whether the decision of prescribers to stop prescribing OxyContin after reformulation was suspicious. In 2011 and 2012, Purdue conducted an epidemiological study of changes to prescribing practices and subjected the prescribers with

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441 In just the ERO market, management advised the Board that Purdue faced competition from Avinza, Exalgo, Embeda, Duragesic, Kadian, Nucynta ER, Opana ER, Dolophine ER, and generics. Nov. 2012 Sales & Mktg. Presentation to Board (PPLPC012000396110) at slide 2. In 2015, management advised the Board that they expected more competitors to be entering the ERO market: Belbuca (made by Endo), Vantrela ER (Teva), ALO-02 (Pfizer), Xtampza ER (Collegium), and MorphaBond ER (Inspirion). *See* Nov. 2015 Budget Presentation to Board (PPLPC063000003207) at -353. *See also* 5/5/17 Email from Craig Landau attaching Diagnostic and Forward Plan (PWG004670879) at -882 ("Numerous competitors have achieved, and in some cases, surpassed our position with their technologies and products through continued pursuit of ADF product development.").

442 *See* 9/12/13 Presentation to Board (PPLPC063000002005) at -009; Nov. 2014 Budget Presentation to Board (PPLP004411368) at -408; Nov. 2013 Budget Presentation (PPLP004409973) at -068.

443 9/23/10 Board Agenda (PWG004349878) at -936.

suspicious changes to further scrutiny under the ADD Program.[444] Based on an analysis of prescribing practices following the reformulation of OxyContin, Purdue's Law Department referred "77 prescribers to the DEA in April 2011."[445]

290. Absent additional information, the Board had no reason to believe that a physician who prescribed ADF OxyContin rather than another prescription analgesic after being detailed by a Purdue sales representative was writing a prescription that was not for legitimate medical purposes. A prescriber who changed a patient's prescription from an IR opioid to ADF OxyContin was making abuse more difficult. A prescriber who changed a patient's prescription from a generic opioid to branded OxyContin was increasing the cost of medication, potentially a financial hindrance to abuse.

291. The Board understood that compliance was built into the E2E program. The November 2013 budget presentation to the Board showed the team structure for managing E2E. Nov. 2013 Budget Presentation (PPLP004409973) at -022. It showed that E2E would be overseen by an Executive Oversight Team that included Purdue's General Counsel (Phil Strassburger) and Chief Compliance Officer (Bert Weinstein) as well as sales and finance executives. *Id.*[446]

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444 2/15/12 Law Department Memo (PWA001433067) (ADD program determination to add to Region Zero a prescriber selected for review based on suspicious changes to prescribing practices following reformulation).

445 8/2/13 Response to LA Times (PPLPC031001086873); *see also* 4/13/11 Email from Bert Weinstein (PPLPC053000051168) at -170 (describing the referral and the spreadsheet provided to the DEA); 4/20/11 Email from Robin Abrams (PWA001487465) (cover email forwarding spreadsheet Purdue sent to DEA identifying suspicious prescribers post-reformulation).

446 *See* 12/17/13 Presentation to E2E Executive Oversight Team (PPLPC014000232245) at slides 24-25, 35-40 (confirming "Compliance monitoring activities" built into program).

D. *Allegations And Evidence Concerning Richard Sackler*

292. No evidence has been adduced that Richard Sackler drafted or approved the content of any Purdue marketing material during the Relevant Period.

293. No evidence has been adduced that Richard Sackler participated in any decisions about what Purdue's marketing would say during the Relevant Period.

294. The Massachusetts AG alleged that a document shows that Richard Sackler "demand[ed] more details about sales and marketing." MA AG FAC ¶304. The cited document shows that Richard Sackler asked Purdue management to "[p]lease circulate to the interested Board members a package of presentations" for Butrans that describe "(1) The marketing program, (2) The sales program, (3) The phase 4 research program, (4) The 2nd gen patch program, [and] (5) The pro forma for the product through 2015."[447] The information that Purdue management provided the Board in response was the "Butrans Commercial Strategy Plan Board Presentation, July 22, 2010," which did not seek Board approval of any marketing statements and which assured the Board that Purdue would provide prescribers "[a]ppropriate fair balance information … including contraindications, warnings, precautions and safety information," and would "[p]roperly educate healthcare professionals on … [t]he full prescribing information and appropriate use of Butrans."[448] Moreover, this email exchange occurred in 2010, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2010.

295. The Massachusetts AG alleged that Richard Sackler "demand[ed] a briefing on how the sales visits were going in the field" for Butrans. MA AG FAC ¶328. The cited document Claimants shows that Richard Sackler said: "I'd like a briefing on the field experience

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447 7/1/10 Email from Richard Sackler (PPLPC012000277480).

448 7/22/10 Butrans Commercial Strategy Plan Board Presentation (PPLPC018000404193) at slides 20, 46.

and intelligence regarding Butrans."[449] This email exchange occurred in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

296. The Massachusetts AG alleged that Richard Sackler "berated sales managers, [and] the managers turned around and fired straight at reps in the field." MA AG FAC ¶198. The cited document shows that Richard Sackler responded to an email from Purdue management informing him that the market share for Butrans increased only slightly, by saying: "This is bad."[450] Moreover, this email exchange occurred in February 2012, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for this period.

297. The Massachusetts AG alleged that Richard Sackler's "micromanagement was so intrusive that staff begged for relief." MA AG FAC ¶¶197, 373. The cited document is an email between Purdue executives discussing Richard Sackler's request for adjustments to the data presented in management's "Butrans Weekly Report." In the cited document, members of Purdue's management expressed annoyance concerning Richard Sackler's requests "for data," but also recognized that "he has a right to know and is highly analytical." The cited document does not mention "micromanagement."[451] Richard Sackler has testified, with respect to Purdue staff complaints about his questions, "They find me a pain in the ass, yes." [452] Moreover, the cited staff complaints were made in March of 2012, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for this period.

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449 1/30/11 Email from Richard Sackler (PPLPC021000352205) at -206.

450 2/7/12 Email from Richard Sackler (PPLPC012000368430).

451 3/8/12 Email from Russell Gasdia (PPLPC012000368569).

452 Richard Sackler MDL Dep. Tr. at 157:15-18 (adding: "Sorry for the vulgarity"), *In re Nat'l Prescription Opiate Litig.*, No. 1:18-md-2804 (N.D. Ohio).

298. The Massachusetts AG alleged that "Richard argued to the Vice President of Sales that a legally required warning about Purdue's opioids wasn't needed." MA AG FAC ¶356. In the cited document, Richard Sackler asked Purdue's management why some information was on one section of the FDA-approved label for Butrans, rather than another.[453] In the cited email, Richard Sackler specifically told Purdue management that "the issue isn't whether [Purdue] can promote" Butrans for post-operative use: his point was limited to where on the label information belonged.[454] Richard Sackler was told that others in the organization shared his concern, but that the FDA rejected the proposal. That ended the matter. Moreover, this email exchange occurred in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

299. The Massachusetts AG alleged that Richard Sackler "pushed staff to sell more of the highest doses and get more pills in each prescription." MA AG FAC ¶232. The cited document shows that Richard Sackler provided comments on presentation slides about a program by management.[455] In the comments, Richard Sackler suggested that prescriptions be reported to the Board "on an adjusted or KG basis."[456] The document said nothing about promoting higher doses or getting more pills in each prescription. Moreover, the cited email was sent in 2008, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.

300. The Massachusetts AG alleged that "Richard Sackler sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times." MA AG FAC ¶240. The cited email from Richard Sackler asks about

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453 7/20/11 Emails with Richard Sackler (PPLPC001000091102) at -102.

454 *Id.*

455 3/8/08 Email from Richard Sackler (PPLPC012000175155) at -157.

456 *Id.*

insurance limitations on the number of tablets covered for much and says nothing about promotion of higher doses.[457] This email was sent in 2008, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.

301. The Massachusetts AG alleged that "Richard Sackler told staff that he was not satisfied with OxyContin sales and demanded a plan to "boost" them." MA AG FAC ¶260. In the cited email, Richard Sackler asked Purdue management to "[p]lease add to the US Board meeting" various items, one of which was a "[p]rogram to boost OxyContin tablets."[458] This email was sent in 2009, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2009. In an Executive Committee Meeting two months earlier, Purdue management had informed the PPI Board that OxyContin sales fell short of expectations because "Mallinckrodt … shipped its supply of generic OxyContin more rapidly than projected."[459] Richard Sackler was requesting information about an issue facing Purdue: the replacement of Purdue's market share by generic competition.

302. The Massachusetts AG alleged that Richard Sackler "insisted that sales rep push the doctors who prescribed the most drugs." MA AG FAC ¶353. The cited email was a reply by Richard Sackler to an email from Purdue's head of sales advising that "[t]he managers all felt that we can improve in our call focus and frequency on high-potential prescribers."[460] Richard Sackler's question asked why "we are calling on non-high potential prescribers."[461] The email

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457 4/22/08 Email from Richard Sackler (PPLPC012000179497) ("What is the status of covered lives now with OxyContin?").

458 7/20/09 Email from Richard Sackler (PPLPC012000232015) at -016.

459 5/20/09 Executive Committee Meeting Notes (PPLPC041000008788) at -788.

460 6/16/11 Email from Richard Sackler (PPLPC012000329706) at -706.

461 *Id.*

does not include a demand "to push doctors who prescribed the most drugs." The email was sent in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for 2011.

303. The Massachusetts AG alleged that Richard Sackler "demand[ed] information about Purdue's opioid savings cards … to make sure he understood the sales tactic down to the smallest detail." MA AG FAC ¶219. The cited email from Richard Sackler shows that he asked questions about a savings card analysis provided by management because the original email explaining the program contained a "typo" that caused "confusion."[462] This email was sent in 2008, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.

304. The Massachusetts AG alleged that Richard Sackler "directed staff to send him weekly reports on OxyContin." MA AG FAC ¶266. In the cited email, Richard Sackler writes: "Please add me to the weekly circulation."[463] This email was sent in 2009, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2009.

305. In these Bankruptcy cases, the Unsecured Creditors Committee alleged that "[i]n 2015, the Board … drafted a resolution that would have limited contact with managers in an effort to stop [Richard] from 'bombarding execs with [] ideas and trying to influence them.'"[464] The cited email discusses a draft resolution by the board of MNP Consulting Limited—not the PPI Board.[465] The draft resolution referenced in the email notes that it is a "Recommendation of the

462 1/30/08 Email from Richard Sackler (PPLPC012000168321) at -321 ("My fault. It was a typo. It is 50 not 500. … Sorry for the confusion.").

463 10/8/09 Email from Richard Sackler (PPLPC012000241515) at -516.

464 Nov. 18, 2020 Unsecured Creditors Committee Reply (ECF No. 2164) at ¶31.

465 6/20/15 Email from Theresa Sackler (PPLPUCC9004448656).

Board of Directors of MNP Consulting Limited."[466] When asked about the draft resolution, Kathe Sackler testified: "if it was a recommendation of the Board of MNP, the MNP Consulting Board, then it related to the international Independent Associated Companies, not to the U.S."[467]

306. In 2011, Richard Sackler attended the first few days of the Butrans Launch Meeting.[468]

307. In 2011**,** Richard Sackler rode along with a sales representative for one day to get "a better idea of the prospects" for Butrans.[469] In consultation with the VP of compliance, Richard Sackler's role was "mum and anonymous."[470] No evidence has been adduced that Richard Sackler promoted any Purdue products during that ride-along. Moreover, the ride-along occurred in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

308. Richard Sackler was deposed in these cases.[471] During his deposition he was not presented with any evidence indicating that he personally approved any Purdue marketing materials or personally participated in any decisions about what Purdue's marketing would say during the Relevant Period. During his deposition, he was not asked and did not testify that he personally approved any Purdue marketing materials or personally participated in any decisions about what Purdue's marketing would say during the Relevant Period.

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466 6/11/15 Draft MNP Decision Document (PPLPUCC9002721550).

467 Kathe Sackler Dep. Tr. 260:14-18.

468 1/31/11 Email from Richard Sackler (PPLPC012000308393).

469 5/3/11 Email from John Stewart (PPLPC042000023301) at -301.

470 6/16/11 Email from Bert Weinstein (PPLPC012000329722) at -722.

471 Richard Sackler Day 1 Dep. Tr.; R. Sackler Day 2 Dep. Tr.

E. *Allegations and Evidence Concerning Jonathan Sackler*

309. No evidence has been adduced that Jonathan Sackler participated in the drafting of or approved the content of any Purdue marketing material during the Relevant Period.

310. No evidence has been adduced that Jonathan Sackler participated in any decisions about what Purdue's marketing would say during the Relevant Period.

311. The Massachusetts AG alleged that "Jonathan Sackler started the year [2012] pressing Sales VP Russell Gasdia for weekly updates on sales." MA AG FAC ¶366. The cited email was an email from Jonathan Sackler to Russell Gasdia (then Purdue's Vice President of Sales), with the subject line "Butrans" asking: "Russ, are you going to resume a weekly (bi-weekly?) update on sales?"[472] Moreover, this email exchange occurred in January 2012, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement for this period.

312. The Massachusetts AG alleged that "Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength." MA AG FAC ¶358. The cited document is a set of notes from a 2011 Board meeting which reflect that Jonathan Sackler "asked for market share change over time for opioid medicines over time --- by strength."[473] This Board meeting occurred in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

313. The Massachusetts AG alleged that "When Jonathan Sackler complained to Stewart about sales ("This is starting to look ugly"), Stewart turned around and ordered Sales VP Russell Gasdia to increase prescriptions." MA AG FAC ¶649. The cited document is a May 25,

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472 1/9/12 Email from Jonathan Sackler (PPLPC012000358983).

473 6/28/11 Board Meeting Notes (PPLPC012000331345) at -345.

2011 email from Jonathan Sackler replying to a report from Purdue's CEO addressing Butrans' lackluster launch: "John, this is starting to look ugly. Let's talk."[474] This email exchange occurred in 2011, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2011.

314. The Massachusetts AG alleged that in 2015 "Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales." MA AG FAC ¶468. The cited document is a 2015 request by Jonathan Sackler for a "briefing on OxyContin market impact of CDC guidelines."[475] Purdue distributed copies of those guidelines to more than 150,000 health care providers.[476]

315. Some Claimants have pointed to a May 2008 email from Jonathan Sackler to Dr. Robert Kaiko, a Purdue employee, in which Jonathan wrote: "I was thinking about the differences between pain patients and drug abusers in their reaction to opioids. Has anybody tried using PET to explore this?"[477] No evidence has been adduced that anyone at Purdue conducted this research. No evidence has been adduced that Jonathan Sackler's question about how

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474 5/25/11 Email from Jonathan Sackler (PPLPC012000326096) -097.

475 12/10/15 Executive Committee Presentation (PPLPC011000073230) at slide 13.

476 Press Release, Purdue Pharma, Purdue Pharma Statement on Massachusetts Complaint (Jan. 31, 2019), https://d279m997dpfwgl.cloudfront.net/wp/2019/01/purdue-statement-1-31.pdf ("In 2016, the Centers for Disease Control (CDC) issued a new guideline for prescribing opioids for chronic pain (CDC Guidelines). Purdue immediately emailed the guidelines to over 150,000 healthcare professionals throughout the country and subsequently distributed thousands of CDC 'tear sheets' setting forth the guideline's recommendations including to doctors in Massachusetts."); *see also* Lisa Miller Dep. Tr. 203:17–19, *State of Oklahoma ex rel. Mike Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816 (Dist. Ct. Cleveland Cty.) ("As far as the CDC, we distributed the CDC to a number of health care professionals through email and link shortly after it came out.").

477 5/15/08 Email from Jonathan Sackler (PPLPC042000013801). *See* NYAG FAC ¶374; First Amended Complaint, *State of Minnesota v. Purdue et al.*, Case File No. 27-CV-18-10788, ¶245.

different groups of people react to opioids had anything to do with the contents of Purdue's marketing. Moreover, this email was sent in 2008, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.

316. The Massachusetts AG alleged that a March 2008 email showed that "Jonathan, Kathe, and Mortimer Sackler were also pushing staff about sales" because Purdue's staff "told those three Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007." MA AG FAC ¶234. The cited document is a chain of emails Jonathan Sackler was copied on, none of which were sent by him and none of which show him pushing staff about anything.[478] The email chain discusses the impact of the savings card (which management explained was a response to pressure from third party payors to "reduc[e] the cost of healthcare," including "high priced meds" like OxyContin) on Purdue's budget and forecast, but says nothing about the contents of Purdue's marketing.[479] Moreover, this email exchange was sent in 2008, and the OIG of HHS confirmed Purdue's compliance with its Corporate Integrity Agreement in 2008.

317. The Massachusetts AG alleges that in 2014 "Jonathan studied collections of news reports and asked staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers." MA AG FAC ¶429. In the cited document, Jonathan Sackler observes that the press had "no apparent focus on makers of IR oxycodone"—*i.e.*, immediate release oxycodone, unlike OxyContin, an extended release oxycodone medication—"and no apparent interest in the distribution chain EXCEPT in the case of FL pain clinics ('pill mills')."[480] The

478 3/16/08 Email from Edward Mahony (PPLPC012000175155).

479 *Id*.

480 1/3/14 Email from Jonathan Sackler (PPLPC020000748356) at -356.

cited document contains no reference to media coverage of "the Sacklers" and has nothing to do with marketing of opioids.

318. The Massachusetts AG alleges that in 2017, "Jonathan Sackler suggested that Purdue launch yet another opioid." MA AG FAC ¶492. The cited document is a 2017 email from Jonathan Sackler asking, "Do you think we should consider an ANDA filing for AD CR morphine?"[481] This question was whether Purdue should consider developing an abuse deterrent form of morphine. No evidence has been adduced that Purdue ever developed an abuse deterrent form of morphine.

F. *Allegations and Evidence Concerning David Sackler*

319. No evidence has been adduced that David Sackler participated in the drafting of or approved the content of any Purdue marketing material during the Relevant Period.

320. No evidence has been adduced that David Sackler participated in any decisions about what Purdue's marketing would say during the Relevant Period.

321. David Sackler was deposed in these cases.[482] During his deposition he was not presented with any evidence indicating that he personally approved any Purdue marketing materials or personally participated in any decisions about what Purdue's marketing would say. During his deposition, he was not asked and did not testify that he personally approved any Purdue marketing materials or personally participated in any decisions about what Purdue's marketing would say during the Relevant Period.

322. The Massachusetts AG alleges that in 2014 David Sackler received a memorandum from his grandfather, Raymond Sackler, which they allege "specifically" concerned

481 11/21/17 Email from Jonathan Sackler (PPLPC016000321333) at -334.

482 David Sackler Dep. Tr.

"putting patients on high doses of opioids for long periods of time." MA AG FAC ¶440. The cited document is a memo that David Sackler received from his grandfather containing a history of Purdue's "Activities Relating … to Acceptance of Abuse Deterrent Formulations of Opioids."[483] The cited document does not discuss Purdue's marketing strategy. David Sackler did not draft the memo or respond to the email.

G. *Allegations and Evidence Concerning Beverly Sackler*

323. No evidence has been adduced that Beverly Sackler participated in the drafting of or approved the content of any Purdue marketing material during the Relevant Period.

324. No evidence has been adduced that Beverly Sackler participated in any decisions about what Purdue's marketing would say during the Relevant Period.

VII. PURDUE FILED A PETITION FOR BANKRUPTCY IN SEPTEMBER 2019

325. Purdue and related entities filed a petition for bankruptcy in September 15, 2019 in the United States Bankruptcy Court for the Southern District of New York. The bankruptcy proceeding is *In re: Purdue Pharma L.P., et al.*, Case No. 19-23649 (RDD).

VIII. THE 2020 GUILTY PLEA AND SETTLEMENTS

326. On October 20, 2020, PPLP agreed to plead guilty to three felony charges (the "**2020 Guilty Plea**") and to settle civilly certain federal claims (the "**Purdue 2020 Civil Settlement**").

A. *Purdue's 2020 Guilty Plea*

327. On October 20, 2020, PPLP entered into a plea agreement with the DOJ, in which it agreed to plead guilty to a three-count Information charging it with conspiracy to defraud the

[483] 5/5/14 Email from Raymond Sackler with Attachment (PWG000412141).

United States and violate the Food Drug & Cosmetics Act and the Federal Anti-Kickback Statute (2020 Guilty Plea, at 1-2).

328. In the 2020 Guilty Plea, Purdue agreed to pay a criminal fine of $3.544 billion and entry of a forfeiture judgment of $2 billion (*id.* at 3). Purdue was required to pay out of pocket only $225 million, in partial satisfaction of the forfeiture judgment. Purdue and the U.S. Department of Justice ("**DOJ**") agreed that (a) the remainder of the forfeiture—$1.775 billion—would be satisfied by the first $1.775 billion in value that Purdue confers on state, tribal and local governmental entities in respect of their claims under Purdue's plan of reorganization (*id.* at 9-10), and (b) the entirety of the $3.544 billion fine would be treated as an allowed, unsubordinated, general unsecured claim (*id*. at 8).

329. In the 2020 Guilty Plea, PPLP admitted to a narrow set of facts in Schedule A to its 2020 Guilty Plea ("**Schedule A**"). *Id.* at 15-18. These admissions do not involve any members of the PPI Board or contain any allegation by DOJ or admission by PPLP that any member of the PPI Board was aware of the charged criminal conduct.

330. There are four parts to Count 1 of the 2020 Guilty Plea, and none of them supports any of the Claimants' claims. PPLP admitted that from approximately May 2007 to March 2017:

a. PPLP included OxyContin prescriptions written by Region Zero HCPs in sales data provided to the DEA in support of annual quota allocation requests. 2020 Guilty Plea, Schedule A p. 16, ¶e.

b. With respect to more than 100 HCPs, PPLP "failed to: (1) report and provide complete and accurate information to DEA about HCPs after the HCPs were flagged by internal anti-diversion programs, in situations in which the Company possessed sufficient information that should have led to a report; and (2) cease detailing HCPs after receiving information suggesting that those HCPs were prescribing opioid products without a legitimate medical purpose and outside the usual course of professional practice…." *Id.* at p. 16, ¶f.

c. PPLP "fail[ed] to account for potential downstream diversion of its products in

reporting sales numbers to DEA as part of its quota requests." *Id.* at 16-17 ¶f.

d. PPLP "knowingly and intentionally conspired and agreed with others to aid and abet HCPs' dispensing, without a legitimate medical purpose and outside the usual course of professional practice … prescription drugs held for sale after shipment in interstate commerce...." *Id.* at 17 ¶g.

331. In Count 2 of the 2020 Guilty Plea, PPLP admitted that from approximately June 2009 to March 2017, it unlawfully offered "payments in the form of speakers fees and other payments (e.g., travel, lodging, consulting fees) to two HCPs with at least one purpose to induce those HCPs to write more prescriptions of Purdue opioid products, for which payment was made in whole or in part under a Federal healthcare program." 2020 Guilty Plea, Schedule A at p. 17 ¶h.

332. In Count 3 of the 2020 Guilty Plea, PPLP admitted that, effective March 1, 2016, it entered into a one-year contract with Practice Fusion—a cloud-based electronic health records platform—to run a Clinical Decision Support program on its platform to alert HCPs to conduct pain assessments and document pain treatment plans. PPLP admitted that "one purpose" of this was to increase Purdue's opioid sales, "portions of which were paid for by Federal health care programs, in violation of the Anti-Kickback Statute…." *Id.* at 17-18 ¶o.

B. *Purdue's 2020 Civil Settlement*

333. At the same time it entered into the 2020 Guilty Plea, Purdue entered into a civil settlement with DOJ for causing false claims to be submitted for payment to federal healthcare programs. *See* Purdue 2020 Civil Settlement at 3-4 ¶II(I).

334. The 2020 Civil Settlement Agreement contained 42 pages of DOJ allegations appended as Addendum A ("Purdue Addendum A"). Purdue expressly denied all of them, except for the limited allegations admitted in Schedule A to the 2020 Guilty Plea that are discussed above. *Id.* at 4 ¶II(K).

C. *The Sackler 2020 Civil Settlement*

335. On October 21, 2020, five of the Former Directors—Richard, David, Mortimer, Kathe and the Estate of Jonathan Sackler—entered into a civil settlement with DOJ (the "**2020 Sackler Settlement**").

336. Like Purdue's 2020 Civil Settlement Agreement, the 2020 Sackler Settlement contains a lengthy addendum of DOJ allegations ("**Sackler Addendum A**"). The Former Directors expressly denied every allegation (*id.* at Recital G).

337. DOJ did not allege in the 2020 Sackler Settlement—or in Purdue's 2020 Guilty Plea or 2020 Civil Settlement—that the Former Directors knew, or should have known, of any of the criminal conduct that Purdue pled to.

EXHIBIT D TO THE EXPERT REPORT OF LAWRENCE HAMERMESH

Cases of Testimony As An Expert At An Evidentiary Hearing Or By Deposition Within The Last Four Years

Capone and Scheinman v. Castleton Commodities International LLC, et al., Index No.: 651794/2015 in the Supreme Court of the State of New York, County of New York

In re Willis Towers Watson Plc Proxy Litigation, Civil Action No. 1:17-Cv-1338) (AJT/JFA), in the United States District Court for the Eastern District of Virginia (Alexandria Division)

Schichinin LLC v. Sprint Corporation, JAMS Arbitration No. 1200054206

Calamos Asset Management, Inc. v. Travelers Casualty and Surety Company of America, C.A. No. 1:18-CV-01510-MN in the United States District Court for the District of Delaware

West v. Access Control Related Enterprises, LLC, et al., C.A. No. N17C-11-137-MMJ CCLD in the Superior Court of the State of Delaware

Wellin v. Wellin, Probate Case No. 2013-GC-10-1029, in the South Carolina Court of Common Pleas, Ninth Judicial Circuit, and *Wellin v. Wellin,* No. 2:2013cv01831, in the United States District Court for the District of South Carolina

In re Starz Appraisal, C.A. No. 12968-VCG, in the Court of Chancery of the State of Delaware

Hill v. J-M Mfg. Co., Inc., Cause No. 2014-64317 in the District Court for Harris County, Texas, 11th Judicial District

Kent v. Formosa Plastics Corp. USA, No. 2014-22302-ASB, in Multidistrict Court, Harris County, Texas, 11th Judicial District

Florida Power Corporation, d/b/a Progress Energy Florida, Inc., Case No. 1:12 CV 1839 in the United States District Court for the Northern District of Ohio, Eastern Division

Kottayil, et al. v. Insys Therapeutics, Inc., et al., No. CV2009-028831, in the Superior Court of the State of Arizona, Maricopa County

Rhoads v. Formosa Plastics Corp. USA, Cause No. 2015-72231-ASB in the Multidistrict District Court, Harris County, Texas, 11th Judicial District

Stilwell Associates, L.P., et al. v. HopFed Bancorp, Inc., et al., C.A. No. 2017-0343-JTL, in the Court of Chancery of the State of Delaware